



Drug	Trade Name (if applicable)	Generic Name	Indication/Use
	Kineret	anakinra	Antirheumatic Agent Used in the treatment of moderate to severe rheumatoid arthritis
	Neulasta	pegfilgrastim	Antineoplastic; Blood Modifier Used to decrease incidence of infection (neutropenia) in some cancer patients
	Neupogen	filgrastim	Antineoplastic; Blood Modifier Used to decrease incidence of infection (neutropenia) in some cancer and leukemia patients

### 1. Amgen's Definition and Understanding of AWP

218. Internally, Amgen defines AWP as "the common basis for reimbursement by payors. AWP may not necessarily reflect the actual purchase price" (Press Release, "Data from Study Shows Aranesp ...", Dec. 9, 2002 ([www.amgen.com](http://www.amgen.com))) or "one of the factors used by Medicare to determine payment for drug charges."

### 2. Amgen Controls the Published AWP for Its Products

219. Amgen has controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia during the Class Period.

### 3. Amgen's AWP Manipulation Benefited Providers at the Expense of the Class

220. Amgen was well aware that its customers' profits depended on reimbursement rates for drugs, and that Amgen's own sales and profits in turn depended on its customers' reimbursement payments and profits:

Our sales depend on payment and reimbursement from third-party payors, and a reduction in the payment rate or reimbursement rate could result in decreased sales of our products.

In both domestic and foreign markets, sales of our products are dependent, in part, on the availability of reimbursement from third-party payors ...we believe that sales of Aranesp and Neulasta are and will be affected by government and private payor reimbursement policies. ...If reimbursement for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our other current or future products, health care providers may limit how much or under what circumstances they



will administer them, which could reduce the use of our products or cause us to reduce the price of our products. This could result in lower product sales or revenues ...

(Amgen 2002 Form 10-K at 43-44).

221. Amgen also knows that several of its drugs compete with other manufacturers' drugs. In some cases, as detailed herein, the competing manufacturers' manipulate the AWP to create a reimbursement advantage for their drugs. Specifically, Amgen's Kineret competes with J&J's Remicade and Immunex's Enbrel; Neupogen competed against Immunex's Leukine; and Aranesp competes against Procrit, J&J's epoetin alfa product. See Amgen's 2001 Form 10-K (P002327-002397). All of these competing drugs are alleged herein to be subject to AWP manipulation. The logical inference is that Amgen also engaged in AWP manipulation for those drugs where the competitors were manipulating and marketing the AWP spread.

222. Amgen also made sure its sales representatives were focused on reimbursement and customer profit motives. A senior Amgen sales manager has publicly stated:

Reps need to understand the insurance system flawlessly. They need to understand the money trail in terms of how a drug gets reimbursed, who reimburses it, and coverage or policy limitations – those are fundamental questions.”

223. Amgen has also established a website ([www.reimbursementconnection.com](http://www.reimbursementconnection.com)) to help providers with reimbursement issues, including information on how to calculate reimbursement for Amgen drugs and Sample Reimbursement Sheets detailing how much Medicare will pay for Amgen drugs. In addition, Amgen maintains a telephone Reimbursement Hotline for providers or their office staffs to call to get help with reimbursement questions.

#### **4. Amgen Provided Free Goods and Other Incentives**

224. In addition to marketing the spread, Amgen has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price.



225. A 1993 OIG Report detailed how Amgen gave substantial year-end rebates to its customers based on their purchases of Epogen. The report noted that Medicare and Medicare beneficiaries did not receive the benefit of any rebates; all monies remained with the provider. There was no way to provide for any rebates on Medicare claim forms, and Amgen's rebates were not provided until year-end:

[T]he effect of the rebates is that it reduces the actual cost of EPO to a dialysis facility, thus increasing their gross profit. Presently, the rebates represent price reductions which benefit the facilities exclusively.

("Review of Epogen Reimbursement," (OIG A-01-02-00506 at 7-8)).

226. By utilizing hidden inducements, Amgen provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

227. Amgen's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs and its use of hidden rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

##### **5. Amgen Concealed Its AWP Manipulation**

228. Amgen deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, as noted above, Amgen gave rebates to its Epogen customers which effectively lowered the true price charged. When OIG asked Amgen for data on its total sales or the total amount of Epogen rebates, Amgen refused to provide such data. ("Review of Epogen Reimbursement," (OIG A-01-02-00506 at 7-8)).

229. In September 2001, the GAO reported that epoetin alfa accounted for the second highest percentage of Medicare expenditures on drugs in 1999, accounting for 9.5% of spending for prescription drugs by Medicare in 1999 and for 3.4% of all Medicare allowed services.

230. As set forth above, Amgen's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

**C. AstraZeneca**

231. AstraZeneca has engaged in an ongoing deliberate scheme to inflate AWP's. The drugs at issue for this defendant are identified in Appendix A and summarized below:

Manufacturer	Brand Name (if applicable)	Generic Name	Drug Description and Indication
ASTRAZENECA	Accolate	zafirlukast	Leukotriene Antagonist (Respiratory Agent) Used in the treatment of asthma
	Armindex	anastrozole	Antiestrogen (Antineoplastic: Hormonal Agonist/Antagonist) Used in the treatment of breast cancer in postmenopausal women
	Atacand	candesartan cilexetil	Angiotension II Receptor Antagonist (Cardiovascular Agent) Used in the treatment of hypertension
	Atacand HCT	candesartan cilexetil-hydrochlorothiazide	Angiotension II Receptor Antagonist With Diuretic (Cardiovascular Agent) Used in the treatment of hypertension
	Casodex	bicalutamide	Antineoplastic Used in the treatment of prostate cancer
	Diprivan	propofol	General Anesthetic Used in the induction or maintenance of anesthesia as part of balanced anesthetic technique
	Entocort	budesonide	Glucocorticoid Used in the treatment of Crohn's disease
	Nexium	esomeprazole magnesium	Proton Pump Inhibitor (Gastrointestinal Agent) Used in the treatment of heartburn and erosive esophagitis
	Nolvadex	tamoxifen citrate	Antiestrogen (Antineoplastic: Hormonal Agonist/Antagonist) Used in the treatment or prevention of breast cancer
	Prilosec	omeprazole	Proton Pump Inhibitor (Gastrointestinal Agent) Used in the treatment of gastric and duodenal ulcers, gastroesophageal reflux disease and erosive esophagitis
	Pulmicort	budesonide (inh)	Glucocorticoid Used for maintenance treatment of asthma
	Rhinocort	budesonide (nasal)	Glucocorticoid Used in the treatment of allergic rhinitis





Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Use
	Seroquel	quetiapine fumarate	Antipsychotic Agent (Psychotherapeutic Agent) Used in the treatment of schizophrenia
	Toprol	metoprolol succinate	Beta Adrenergic Blocking Agent (Cardiovascular Agent) Used in the treatment of hypertension, angina pectoris and heart failure
	Zestril	lisinopril	Angiotension Converting Enzyme Inhibitor (Cardiovascular Agent) Used in the treatment of hypertension and heart failure
	Zoladex	goserelin acetate	Gonadotropin Releasing Hormone Analogue (Antineoplastic: Hormonal Agonist/Antagonist) Used in the treatment of prostate and advanced breast cancer
	Zomig	zolmitriptan	Serotonin Receptor Agonist (Migraine Preparation) Used in the treatment of migraines

### 1. AstraZeneca Has Been the Target of a Government Investigation

232. In connection with its scheme to inflate AWP's, AstraZeneca has been investigated by the United States Department of Justice. In January 2002, a federal grand jury in Wilmington, Delaware returned an indictment accusing a New Jersey doctor of conspiring with AstraZeneca to resell free samples of Zoladex® that AstraZeneca sales representatives had given the doctor. The indictment alleges that AstraZeneca (i) sold Zoladex® to the New Jersey doctor and others at prices substantially below the AWP reported by AstraZeneca, and (ii) provided the New Jersey doctor with materials showing how much more profit he could make by using Zoladex® instead of its competitor, Lupron®.

233. In response to the government's subpoena, AstraZeneca appears to have produced documents related to Zoladex only.

### 2. AstraZeneca's Definition and Understanding of AWP

234. In AstraZeneca's Guide to Coverage and Reimbursement, AstraZeneca defines AWP as follows:



**Average Wholesale Price (AWP):** The composite wholesale price charged on a specific commodity that is assigned by the drug manufacturer and is listed in either the Red Book or Blue Book. AWP is often used by third-party payers as a basis for reimbursement.

(AZ0052597) (Confidential). Thus, by its own definition, AstraZeneca recognizes that: (i) AWP should be an average of actual wholesale prices; (ii) the drug manufacturers control the published AWP; and (iii) the published AWP directly affect the payments made by the Class.

**3. AstraZeneca Controls the Published AWP for Its Products**

235. AstraZeneca has controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia during the Class Period. In one internal marketing memorandum, AstraZeneca recommended:

We take a price increase in December 1995. By doing this, we can inform the Red Book of this increase and it will go into the Red Book for January 1996. This is critical, so that the state Medicare carriers can recognize our new price in January. Typically, the state carriers use the January Red Book and the July Red Book for their reimbursement price of Medicare reimbursed products. Last year when we took the price increase in February there were some Medicare carriers who did not change their reimbursement price until September. Also TAP notifies Red Book 1 month before the price change. We are at a competitive disadvantage with our audience.

(AZ0021838) (Highly Confidential).

**4. AstraZeneca's AWP Manipulation Benefited Providers at the Expense of the Class**

236. The purpose of AstraZeneca's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class.

a. In one internal marketing memorandum, AstraZeneca recognized the profits to providers from the inflation of AWP: "The market we are in wants a more expensive Zoladex, because the doctor can make more money." (AZ0021838) (Highly Confidential).



b. Similarly, in its agreements with PBMs, AstraZeneca guaranteed that it would maintain a spread between AWP and AWC (average wholesale cost) in order to ensure a profit to PBMs at the expense of the Class. (AZ0036207) (Highly Confidential). For example, in its agreement with Caremark, AstraZeneca stated:

ZENECA WILL REIMBURSE CAREMARK FOR THE DIFFERENCE BETWEEN THE AMOUNT COLLECTED BY CAREMARK ON EACH PATIENT UNIT SOLD AND AWP AT THE TIME THE UNIT WAS DISPENSED. CAREMARK WILL HAVE EXERCISED BEST EFFORTS TO COLLECT THE FULL AWP FROM THE 3RD PARTY PAYER AND THE PATIENT PRIOR TO SUBMISSION TO ZENECA.

(AZ0036208) (Highly Confidential).

c. AstraZeneca recognized that its practices were at the expense of the Class:

BECAUSE OF OUR STEEP DISCOUNTING, NEARLY HALF THE PROFIT TO BE REALIZED WITH ZOLADEX IS PAID BY MEDICARE. AND SINCE MEDICARE IS THE QUICKEST AND MOST DEPENDABLE PAYOR, THIS WAS SEEN AS AN ENORMOUS BENEFIT. THE OTHER HALF OF THE PROFIT WAS FROM THE PATIENT CO PAY OR SECONDARY INSURANCE . . . .

(AZ0037011) (Highly Confidential).

**AstraZeneca Manipulated and Marketed the AWP for Zoladex**

237. AstraZeneca stated an inflated AWP for Zoladex and marketed the resulting spread during the Class Period. AstraZeneca's documents reveal an intense competition with TAP Pharmaceuticals and its drug Lupron, focusing primarily on the spreads available to physicians between Zoladex and Lupron.

238. For instance, one internal chart touts the greater spread that can be reaped from the inflated AWP for Zoladex over the AWP for Lupron:

	AWP	AWP minus 5%	Current Cost (1 depot)	Return to Practice 1 depot	Current Max Discount 29.5% vs 50%	Return to Practice at Max.
Lupron 3-month depot	\$1,622.68	\$1,541.55	\$1,297.50	\$244.05	\$915.00	\$626.55



	ASP	ASP minus 2%	Current Price (\$/unit)	Current Price (\$/box)	Current Price (\$/box) minus 2%	Current Price (\$/box)
Zoladex 3- month depot	\$1,231.53	\$1,169.95	\$985.22	\$184.73	\$492.61	\$677.34

(AZ 0055816) (Highly Confidential).

239. Another document announcing new pricing for Zoladex states:

With a purchase of 72+ depots of ZOLADEX and the additional 2% for paying within 30 days yields the doctor a \$133.67 profit margin with ZOLADEX vs \$133.50 with a purchase of 101+ depots of Lupron. For those offices that purchase between 60-100 depots of Lupron monthly, they can increase their profit margin greatly by purchasing ZOLADEX.

(AZ 0037019) (Highly Confidential).

240. Moreover, AstraZeneca repeatedly tried to educate providers regarding the Medicare reimbursement system and the benefits to the providers for Zoladex utilization. For example in a document sent to providers AstraZeneca states:



The following is a cost comparison of Zoladex® vs Lupron® 7.5 mg where Zoladex® is purchased under the buying power of the Urology Purchasing Group, St. Louis, Mo. The calculations reflect prices/discounts effective as of 2/1/94.

	ZOLADEX	LUPRON			
Quantity	1	1-11	12-25	26-50	Year 01/94
Direct Drug Cost	\$344.97	\$371.00	\$348.99	\$392.50	\$
Medicare % Claim	\$344.76 - 20.3%	\$463.75 - 20.3%	\$463.75 - 20.3%	\$463.75 - 20.3%	\$463.75 - 20.3%
Medicare Payment to MD	\$275.21	\$371.00	\$371.00	\$371.00	\$371.00
Patient / 3rd Party Payment*	\$344.76 - \$275.21 \$ 69.55	\$463.75 - \$371.00 \$ 92.75	\$463.75 - \$371.00 \$ 92.75	\$463.75 - \$371.00 \$ 92.75	\$463.75 - \$371.00 \$ 92.75
Medicare State Direct Drug Cost	\$344.76 - \$344.97	\$463.75 - \$371.00	\$463.75 - \$348.99	\$463.75 - \$392.50	\$463.75 - _____
Total Profit Per Injection	\$ 98.79	\$ 92.75	\$108.75	\$101.25	
Difference		\$ 6.04	\$ 4.96	\$ 12.46	\$ _____
Percent Profit per Injection	40%	25%	29%	26%	____%
Additional Cost outlay of Lupron vs Zoladex (Direct Cost vs Direct Cost)		\$125.00	\$114.00	\$106.50	\$ _____

**ILLUSTRATION:** If your office uses between 12 and 25 Lupron® units per month, your total "profit" per injection, over Zoladex, is \$4.96 but your additional outlay per Lupron injection is \$114.00. This represents and unnecessary tie up of corporate monies. Based on 12 Lupron injections per month, your office has "tied up" \$1,368.00 to achieve a "profit" of \$59.52. In this example, Zoladex represents a 40% return on investment vs. 29% for Lupron.

\* Calculations assume a 100% collection of monies from patient or 3rd party. If Lupron® is used instead of Zoladex® and the 20% is not collected, then the office has lost \$23.00 per injection (\$92.75 - \$69.75 = \$23.00).

01-25-0416

(AZ0046085) (Highly Confidential).



241. Internal AstraZeneca documents reveal that AstraZeneca was directly marketing the spread to physicians. A memo announcing price changes for Zoladex states:

We have raised AWP and AWC by 7% and have increased our discount level higher at all purchasing tiers.

Pricing on Zoladex 3-month is as follows:

Discount		AWP	Cost
1-5 depots	0	1206.49	966.79
6-11 depots	11	1206.49	860.44
12-23 depots	15	1206.49	821.77
24-47 depots	17	1206.49	802.44
48-59 depots	20	1206.49	773.43
60-71 depots	22	1206.49	754.10
72-96 depots	24	1206.49	734.76
96-191 depots	25	1206.49	725.09
192 +	30	1206.49	676.75

Zoladex AWP has been priced at a 5% premium above 3 times the Zoladex 1-month depot. The discount levels have been increased also.

(AZ 0024566-67.)

242. Thus, at the same time AstraZeneca was raising the AWP for Zoladex, it was lowering the real price to providers (by giving bigger discounts), which served to widen the spread.

243. Another document sets forth the difference between the purchase price and the AWP at various volume levels. Note that even with no volume discount, a provider is still making at least a \$71.00 profit per unit on Zoladex ( $\$358.55 - 286.84 = 71.71$ ):

#### NEW LOWER CASE QUANTITY DISCOUNT ZOLADEX PRICING

UNITS	AWP	COST	DISCOUNT	LESS 2%
1-5	\$358.55	\$286.84	0%	\$281.10
6-11	\$358.55	\$269.63	6%	\$264.24
12-23	\$358.55	\$261.02	9%	\$255.80
24-47	\$358.55	\$252.42	12%	\$247.37
48-59	\$358.55	\$243.81	15%	\$238.93
60-71	\$358.55	\$235.21	18%	\$230.50
72+	\$358.55	\$229.47	20%	\$224.88





(P003060.)

244. The same document goes on to tout the practice's ability to make more profit, or return on investment, by exploiting the AWP scheme:

Thank you for your time and listening ear on Monday, April 17. As discussed, I am offering a proposal to switch Lupron patients to Zoladex. Zeneca Pharmaceuticals now has new volume pricing, with a 20% maximum discount, for Zoladex. What this will offer the practice is an opportunity to save money, realize a better return on investment, achieve the same profit you currently have with our competitor and free up a substantial amount of working capital. Zoladex will also save the patient money and the system money.

Based on a comparison of Zoladex and Lupron, if 480 depots are used annually Zoladex will save the practice \$57,177.60 a year. Your dollar return to the practice is now slightly higher with Zoladex. This rate of return for Zoladex is now 59% compared to Lupron's 39%

(P003058.)

245. Another AstraZeneca document even more explicitly demonstrates to providers how they can profit from the AWP scheme, in excess of \$64,000 per year:

## ZOLADEX

Direct Pricing	Medicare AWP	\$\$Return / % Return	
72+ \$224.88	\$358.55	\$133.67	59%
72x\$224.88=\$16,191.38	72x\$358.55=\$25,815.60	\$9,624.24	59%
<i>based on your use of 480 depots annually, with our 2% discount these are the comparisons</i>			
\$107,942.40	\$172,104.00	\$64,161.60	59%

(P003058.)

246. According to a September 2001 GAO report, the discount from AWP for medical providers who purchased AstraZeneca's Zoladex and billed Medicare was between 21.9% and 22.3%. ("Payments for Covered Outpatient Drugs Exceed Providers' Cost, Sept. 2001")

(P005546-78.)



247. AstraZeneca, through its employees and agents, also provided millions of dollars worth of free samples of its drugs to providers. The free samples would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class. Moreover, at least as to Zoladex®, AstraZeneca sales representatives specifically told providers that they could and should bill for the free samples.

248. A written proposal from AstraZeneca Sales representative Randy Payne dated July 17, 1995 encourages a urology practice to switch all of their patients to Zoladex and states: “AS AN ADDED INCENTIVE, ZENECA WILL PROVIDE YOU WITH 50 FREE DEPOTS (over \$11,900 worth of product) FOR THE INITIAL CONVERSION TO ZOLADEX.” (P003059.)

249. As set forth above, AstraZeneca’s scheme to inflate its reported AWP’s for Zoladex, market the resulting spread, and channel to providers “free” goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

**D. The Aventis Group (Aventis, Pharma, Hoechst and Behring)**

250. Aventis engages in an organization-wide and deliberate scheme to inflate AWP’s. Aventis has stated fraudulent AWP’s for all or almost all of its drugs, including those set forth below. The specific drugs of Aventis for which relief is sought in this case are set forth in Appendix A and are as follows:

Manufacturer	Product Name (if applicable)	Generic Name	Therapeutic Category/Description
AVENTIS GROUP (Aventis, Pharma, Hoechst and Behring)	Allegra	fexofenadine	Antihistamine Used for the relief of symptoms of seasonal allergic rhinitis
	Allegra-D	fexofenadine pseudoephedrine	Antihistamine Used for the relief of symptoms of seasonal allergic rhinitis



Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Use
	Amaryl	glimepiride	Antidiabetic Used to lower blood glucose in Type II diabetes patients
	Anzemet	dolasetron mesylate	Antineoplastic Used to prevent nausea and vomiting after chemotherapy or operation
	Arava	leflunomide	Antirheumatic Used in the treatment of active rheumatoid arthritis
	Azmacort	triamcinolone aceonide (inh)	Steroidal Anti-Inflammatory Agent (Respiratory Agent) Used for maintenance treatment of asthma
	Calcimar	calcitonin salmon	Parathyroid Agent Used in the treatment of blood calcium levels and to increase the level of calcium in the bones
	Carafate	sucralfate	Duodenal Ulcer Adherent Complex (Gastrointestinal Agent) Used in the treatment and maintenance therapy of duodenal ulcer
	Cardizem	diltiazem	Calcium Channel Blocker (Cardiovascular Agent) Used in the treatment of angina and hypertension
	Gammar P.I.V.	immune globulin	Immunizing Agent Used as a maintenance therapy in patients with compromised immune systems
	Intal	cromolyn sodium	Antiasthmatic Used to treat allergic rhinitis and severe perennial bronchial asthma
	Nasacort	triamcinolone acetanide (nasal)	Steroidal Anti-Inflammatory Agent (Nasal Preparation) Used for nasal treatment of allergic rhinitis symptoms
	Taxotere	docetaxel	Antineoplastic Used in the treatment of breast or lung cancer after failed chemotherapy
	Trental	pentoxifylline	Blood Viscosity-Reducing Agent (Blood Modifier) Used to improve the flow of blood through blood vessels



**1. Aventis Has Been the Target of Government Investigations**

251. In connection with its scheme to inflate AWP's, Aventis has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Commerce Committee of the U.S. House of Representatives, the Attorney General for the State of Texas, the Attorney General for the State of California, and the State of California Department of Justice Bureau of Medi-Cal Fraud and Elder Abuse.

**2. Aventis' Definition and Understanding of AWP**

252. Internal documents recently produced by Aventis reveal the definition of AWP used and understood by Aventis and its predecessor companies. Specifically, a November 1992 internal newsletter at Armour Pharmaceutical Company (a predecessor company to Centeon LLC, later known as Aventis Behring) states:

"AWP" is common language among insurance carriers (state, federal and private). The acronym stands for Average Wholesale Price. AWP's are set by manufacturers as a "suggested retail" for the products they produce. *These figures represent a reasonable profit margin to healthcare providers and as such are widely referenced by insurance carriers when setting reasonable and customary rates of reimbursement.*

Average Wholesale Prices are printed in Red Book Drug Topics and Blue Book. Both serve as data resources to all state Medicaid programs. Each publication lists the drugs by brand name in alphabetical order with its corresponding descriptions.

(ABAWP 008990-91) (Highly Confidential) (emphasis added).

253. Aventis possessed the *Red Book's* definition of Average Wholesale Price:

Average wholesale price (AWP) is the standardized cost of a drug, which managed care plans frequently use for determining drug benefits. The AWP is determined through reference to a common source of price information, such as the American Druggist's *Blue Book*, which lists the costs charged for an undiscounted drug to a pharmacy by a large group of pharmaceutical wholesale suppliers. AWP's are set by pharmaceutical manufacturers and supplied to all pricing data banks for publication.

(ABAWP 012067) (Highly Confidential).



### 3. Aventis Controls the Published AWP for Its Products

254. Aventis controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia during the Class Period.

a. For example, on December 29, 1997, Rhone-Poulenc Rorer (a subsidiary of Rhone Poulenc SA, which merged with Hoechst AG to form Aventis in 1999) submitted a list of AWP price increases effective January 1, 1998 to both Medi-Span and First Data Bank. Aventis instructed Medi-Span and First Data Bank to “change [their] records accordingly to reflect the new prices.” (AV-AAA-001054) (Confidential). Similar letters requesting price changes for 1999 were sent to Medi-Span and First Data Bank by Aventis on December 29, 1998. (AV-AAA-001047) (Highly Confidential), (AV-AAA-001050) (Highly Confidential), and price changes for 1997 on December 23, 1996 (AV-AAA-001066) (Highly Confidential).

b. An April 1, 1998 letter from Centeon notifies Medical Economics (the *Red Book*) that effective April 1, 1998, it “has raised AWP pricing” for Bioclote and Monoclate. (ABAWP 005314) (Highly Confidential).

### 4. Aventis’ AWP Manipulation Benefited Providers at the Expense of the Class

255. The purpose of Aventis’ manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class.

256. Aventis knew that AWP manipulation, and the related marketing of an AWP spread, was improper. An internal Aventis (Centeon) document, in pertinent part, states – in large, bold print:

**ATTENTION!**

**SELLING AGAINST AWP**

This is not an option.

Traditionally, some manufacturers have promoted differences in AWP as a means to sell their products. Centeon does not do this,



and we hope to hear from you if you learn that any other manufacturer (sic) are using this tactic.

Some pharmaceutical manufacturers set high AWP as a means of securing market shares for their drugs. Although not illegal, the intensity of government scrutiny of this and other pharmaceutical manufacturer pricing practices is increasing. The inspector general is looking at prices for big-ticket drugs

\*\*\*

At the risk of being redundant it is imperative to stress that AWP can not (sic) be used in the content of selling any of our products. If you are made aware, either orally or through written correspondence, of any manufacturer using this form of sales tactic immediately report such findings to Gene Hull and appropriate steps will be taken.

(ABAWP 000855) (Highly Confidential).

257. Nonetheless, Aventis (Centeon) routinely promoted differences in AWP in marketing its numerous products. In seminar materials used in conjunction with an "Oncology University Anzemet Workshop" held in 1998, Aventis explained to attendees how its AWP spread could be exploited. Aventis offered the following definition and example of AWP spread:

#### **SPREAD**

- Difference between acquisition cost (AC) and reimbursement (Profit, Margin, etc.).
- Example for Anzemet
  - AC = \$68 for 100 mg vial
  - AWP = \$166.50
  - AWP - 5% = \$158.18
  - 80/20 = \$126.54/\$31.64
  - Spread = \$58.54 + \$31.64 = \$90.18

(AV-AAA-02242-56) (Highly Confidential).

258. Aventis, through its employees and agents, also provided free samples of its drugs to providers. (ABAWP 000089) (Highly Confidential) (ABAWP 000811) (Highly Confidential). The free samples would be used to offset the total cost associated with purchases of its drugs,





thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class. In fact, a 1995 “SALES AND FREE GOODS STATUS” memo reveals that Aventis (Armour) issued millions of “free goods units” to a single customer alone. (ABAWP 000220-25) (Highly Confidential).

259. Further, just as Aventis motivates providers to administer drugs based on the AWP, Aventis rewards PBMs based on the degree of influence they exert to drive utilization of Aventis products. (AV-AAA-000197-99) (Highly Confidential).

##### **5. Specific Aventis AWP Documented by the DOJ**

260. In a report published by the DHHS (AB-00-86), the DOJ documented at least 15 instances where the published AWP for various dosages of 4 drugs manufactured by Aventis were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 4 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ’s determination of an accurate AWP for that particular dosage, based upon wholesalers’ price lists, with the AWP reported by Aventis in the 2001 *Red Book*.

Drug	2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Anzemet Injectable (dolasetron mesylate)	\$166.50	\$74.08	\$92.42	125%
Factor VIII/ Bioclone	\$1.25	\$.91	\$.34	37%
Factor VIII/ Helixate	\$1.18	\$.78	\$.40	51%
Gammar (immune globulin)	\$400.00	\$296.67	\$103.33	35%

(P006299-P006316).

261. An OIG report (*see* “Medicare Reimbursement of Prescription Drugs,” OEI-03-00-00310, Jan. 2001) further revealed that: (i) the AWP for all immune globulin 5 mg doses listed in the 1997 *Red Book* were inflated by an average spread of 32.21%; (ii) a 10 mg dose of Anzemet had a Medicare Median of \$14.82 and a Catalog Median of \$8.29, resulting in a spread



of 78.76%; and (iii) a 20 mg dose of Taxotere had a Medicare Median of \$283.65 and a Catalog Median of \$8.29, resulting in a spread of 18.75%. (P006398-006424).

#### 6. Additional Evidence Concerning Anzemet

262. Aventis distributed a “Reimbursement Spreadsheet” to be utilized by its sales personnel to demonstrate to “private practice office” customers the “financial advantages” of its drug, Anzemet, compared to Zofran and Kytril based on Aventis’ established AWP and acquisition price (total reimbursement through Medicare). (AV-AAA-001190-93) (Highly Confidential). Aventis also communicated to its sales staff on December 7, 1998 that “Anzemet still [held] the advantage on spread” following a Kytril price increase. (AV-AAA-002291) (Highly Confidential).

263. Another Aventis internal document also addresses how a particular Aventis customer might increase its margin choosing Anzemet over the competition:

Cost and Reimbursement: OnCare has negotiated a very favorable contract with Hoechst Marion Roussel [an Aventis predecessor company], manufacturer of Anzemet. Our cost from OTN for the Anzemet 100 mg/ml vial is reduced from approximately \$70 ea. to \$62.50. In addition there will be quarterly rebates further reducing the cost to \$61.25. The AWP is \$149.88, making the margin \$88.63. Additional returns can be realized by using 1.8 mg/kg as recommended in the package insert. For example, for a patient weighing 70Kg, the dose is 126 mg, requiring 2 vials. Since the vial is single use, you may bill for both vials: total cost is \$122.50, the AWP is \$299.76, the net is \$177.26 (assuming reimbursement at AWP). By comparison the current margin for 0.7 of Kytril is \$54.89. For 1 mg it is \$78.42. If there is a price increase in 1999 (which we expect) our prices are protected, however the AWP will go up, further increasing the margin. The contract makes Anzemet the preferred 5-HT3 antiemetic drug for OnCare.

(AV-AAA-001523) (Highly Confidential). Other customers received promotional materials reflecting a significant spread between the unit price and AWP for Anzemet – and touting a “Reimbursement and Patient Assistance Program Hotline.” (AV-AAA-001619-23) (Confidential).



264. A government investigation revealed similar inflated pricing implemented by Aventis with respect to the injectable form of Anzemet. In a September 28, 2000 letter to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, U.S. Rep. Pete Stark provided a synopsis of the scheme implemented by Aventis (Hoechst):

The following chart represents a comparison of Hoechst's fraudulent price representations for its injectable form of the drug versus the truthful prices paid by the industry insider. It is [sic] also compares Hoechst's price representations for the tablet form of Anzemet and the insider's true prices. It is extremely interesting that Hoechst did not create a spread for its tablet form of Anzemet but only the injectable form. This is because Medicare reimburses Doctors for the injectable form of this drug and by giving them a profit, can influence prescribing. The tablet form is dispensed by pharmacists, who accept the Doctor's order. And this underscores the frustration that federal and state regulators have experienced in their attempts to estimate the truthful prices being paid by providers in the marketplace for prescription drugs and underscores the fact that, if we cannot rely upon the drug companies to make honest and truthful representations of their prices, Congress will be left with no alternative other than to legislate price controls.

NDC No:	Unit Size/ Type	Quantity	Net Price as Represented to Florida Medicaid	True Wholesale Price	Variance
0088-1206-32	100 mg/5 ml Injectable	1	\$124.90	\$70.00	Represented price 78% higher than true wholesale price.

(P007548-007588).

#### **7. Additional Evidence Concerning Gammar**

265. Similarly, Aventis increased AWP's for its Gammar product line to keep provider and intermediary reimbursement levels competitive with those created by the inflated AWP's of other manufacturers. A May 8, 1996 Aventis (Centeon) Interoffice Correspondence memo states:

Effective June 1, 1996, we will be revising our AVERAGE WHOLESAL PRICE for our Gammar P iv product line. We are implementing this change based on feedback from the field. Alpha and Bayer have recently increased their AWP pricing on



Gammimmune 10% and Venoglobulin S 10%. They are presently priced at \$75 and \$80 per gram respectively. . . . This change will help us maintain a competitive balance in the marketplace.

(ABAWP 004767) (Highly Confidential).

266. Centeon interoffice correspondence, dated June 23, 1999, reveals that a Centeon employee provided a representative of First Data Bank with the following information regarding Centeon's AWP for Gammar:

She asked me to validate Centeon's AWP and wholesale list price for Gammar PIV 5 and 10 gram vials.

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I gave her the following info:

"Currently it is not Centeon's business practice to sell Gammar PIV to wholesalers. But should a wholesaler place an order, our wholesale list price is \$52/gram, or \$260 for 5 gram vial, and \$520 for 10 gram vial."

"Centeon's suggested AWP is \$400 for 5 gram vial, and \$800 for 10 gram vial. This is pricing as reported to First Data Bank, but we do not sell product at these prices."

(ABAWP 005315) (Highly Confidential).

267. U.S. Rep. Thomas J. Bliley, in a May 4, 2000 letter to the CEO of Aventis (Behring), also stated concerns regarding Aventis' pricing of Gammar:

The Office of Inspector General (OIG) at the Department of Health and Human Services determined that the Medicare-allowed amount for immune globulin, a pharmaceutical product sold by your company under the name Gammar, in Fiscal Year 1996 was \$42.21. The OIG further estimated that the actual wholesale price of this drug was \$16.12 and the highest available wholesale price that the OIG was able to identify was \$32.11.

(P006962-P006966).

#### **8. Inflated AWP's From Aventis' Price Lists**

268. In response to government subpoenas, Aventis produced numerous price lists setting forth spreads between AWP's and prices offered to wholesalers, providers and other



intermediaries. A review of those price lists reveals that Aventis has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical.

269. A March 4, 1997 price list issued by Arcola Laboratories (a division of Rhonel-Poulenc Rorer Pharmaceuticals sets the AWP for Calcimar (calcitonin-salmon) at \$31.35, with a cost of \$12.00 – for a spread of 161%. (AV-AAA-000705).

270. As set forth above, Aventis' scheme to inflate its reported AWP and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

#### **9. Aventis Concealed its AWP Manipulation**

271. Aventis deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, in response to a May 26, 1995 fax request from *Red Book*, Aventis refused to provide Wholesale Acquisition Cost (WAC) for products it listed in the *Red Book* database – in spite of *Red Book's* assurances that WAC information would be distributed via electronic means only. (ABAWP 008420) (Highly Confidential). Aventis effectively hid the AWP spread from Plaintiffs and the Class.

#### **E. Baxter**

272. Baxter engages in an organization-wide and deliberate scheme to inflate AWP. Baxter has stated fraudulent AWP for all or almost all of its drugs those set forth below. The specific drugs of Baxter for which relief is sought in this case are set forth in Appendix A and are summarized below:



Manufacturer	Trade Name (if applicable)	Generic Name	Therapeutic Category/Usage
BAXTER	Aggrastat	tirofiban hydrochloride	Glycoprotein Receptor Inhibitor (Blood Modifier) Used in the treatment of acute coronary symptoms
	Ativan	lorazepam	Antianxiety Agent (Psychotherapeutic Agent); Anticonvulsant Used to relieve anxiety and treat insomnia
	Bebulin VH	factor ix (systemic)	Antihemorrhagic Agent Used to treat hemophilia B
	Brevibloc	esmolol hcl	Autonomic Nervous System Agent Used in the treatment of tachyarrhythmias in critical situations
	Buminate	albumin (human)	Plasma Fraction (Blood Modifier) Used in the treatment of hypovolemia and hypoalbuminemia
	Claforan	cephalosporin (systemic)	Antibacterial Agent (Anti-Infective Agent) Used in the treatment of infections caused by bacteria
	Gammagard S/D	immune globulin solution	Antibacterial Agent (Anti-Infective Agent) Used to prevent or treat some illnesses.
	Gentran	dextran	Blood Derivative; Blood Modifier Used in the emergency treatment of shock
	Holoxan/Ifex	ifosfamide	Antineoplastic Used in the treatment of various forms of cancer
	Iveegam EN	immune globulin iv	Antibacterial Agent (Anti-Infective Agent) Used as replacement therapy in patients with primary immunodeficiency syndromes
	Osmitol	mannitol	Osmotic Diuretic Used to promote diureses during treatment of acute kidney failure. Also used to reduce intraocular and intracranial pressure
	Recombinate	factor viii	Antihemophilic Factor Used to induce blood clotting
	Travasol	amino acid	Dietary Supplement Used for nutritional support in cancer patients
	Vancocin HCl	vancomycin hydrochloride	Antibacterial Agent (Anti-Infective Agent) Used in the treatment of infections caused by bacteria
		cisplatin	Antineoplastic Used to treat cancer of the bladder, ovaries, and testicles
		dextrose	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids





Manufacturer	Brand Name (if applicable)	Generic Name (if applicable)	Indication/Category/Usage
		doxorubicin hcl	Antineoplastic Used in the treatment of various forms of cancer
		gentamicin	Antibacterial Agent (Anti-Infective Agent) Used to treat serious bacterial infections
		heparin	Anticoagulant (Cardiovascular Agent) Used to decrease the clotting ability of the blood
		sodium chloride	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion

### 1. Baxter Has Been the Target of Government Investigations

273. Baxter has been investigated by the United States Department of Justice, Department of Health and Human Services Office of Inspector General, the Attorney General for the State of California, the Attorney General for the State of Texas, the Attorney General for the State of Illinois, and the Committee on Commerce of the House of Representatives.

274. These investigations confirm that Baxter has engaged in a deliberate scheme to inflate AWP's for many or most of its drugs. A Baxter document made public as a result of the congressional investigation entitled, "Confidential – Baxter Internal Use Only," acknowledged that: "Increasing AWP's was a large part of our negotiations with the large homecare companies." Baxter further admitted in internal documents that homecare companies that reimburse based on AWP make a significantly higher margin. Thus, Baxter's own documents demonstrate its active participation in the scheme to artificially inflate AWP's.

### 2. Baxter's Definition and Understanding of AWP

275. Despite its manipulation, Baxter understood what AWP should mean: "The average price that a pharmacy (or provider) pays for the product from their drug wholesaler or distributor." (BAX MDL 0011378) (Highly Confidential). Contrary to its own definition of



AWP, Baxter nonetheless set AWP for its drugs far in excess of what providers paid for those drugs.

### 3. Baxter Controls the Published AWP for its Products

276. Baxter has controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, a September 7, 1995 inter-office memorandum provides:

I have been in contact with both *Red Book* and Medispan earlier this year about our AWP. I told them that we will not be raising our AWP for FVIII in 1995, and will only increase IGIV in the event of a label change. There are a few general rules about AWP adjustments.

- A manufacturer may raise AWP at any time in the year. There is a monthly publication called the *Red Book* Update that lists all changes to the April publication (the big red book).
- If a manufacturer does decide to increase AWP: - payors want a justification for the increase. This is why we typically don't increase the AWP unless we have a label change, product enhancement . . . .

(BAX MDL 0004754) (Highly Confidential).

### 4. Baxter's AWP Manipulation Benefited Providers at the Expense of the Class

277. In at least one internal document, Baxter recognized that deliberate manipulation of the spread was being wrongly used to gain competitive advantage by manufacturers:

*The deliberate manipulation of AWP or WAC prices is a problem that we need to address. The spread between acquisition cost and AWP/WAC is direct profit for customers, and is being used to increase product positioning in the market by certain manufacturers.*

(BAX MDL 0012778) (Highly Confidential) (emphasis added).

278. Despite this recognition, Baxter nonetheless continued to manipulate its AWP in order to maintain the competitiveness of its own products based upon the spread. In a January 6,



1992 inter-office memorandum, Baxter informs its employees how to respond to inquiries concerning AWP increases for Baxter products:

If you receive inquiries from customers or payors questioning our rationale on this recent increase in Published AWP for Baxter products please communicate the following message and no more.

If any further information is needed please send the inquiry to me directly.

A recent review of industry published direct prices and AWP's revealed that Baxter's published AWP's are significantly lower than competitive AWP's. We have therefore adjusted our AWP's to meet competitive levels.

Most of Baxter General Healthcare Division's products are sold to distributors at negotiated contract prices that are different from AWP's. We do not have knowledge of or input to the actual prices charged to the provider by our distributors. The contracted prices to our distributors will not be directly affected by this change in AWP's.

(BAX MDL 0004210) (Highly Confidential).

279. In addition, Baxter's marketing and sales documents, which were prepared and disseminated to its employees and agents via the U.S. mail and interstate wire facilities, compared the costs of their respective drugs to those of their respective competitors and were intended to induce physicians to use Baxter drugs and shift market share in its favor. Other documents created and disseminated by Baxter compared the AWP and the actual "cost" of their respective drugs, so that medical providers could easily see the different "return-to-practice" amounts available for different levels of purchase.

##### **5. Specific Baxter AWP's Documented by the DOJ**

280. In a report published by the DHHS (AB-00-86), the DOJ documented at least 41 instances where the published AWP's for various dosages of drugs manufactured by Baxter were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the four drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular



dosage, based upon wholesalers' price lists, with the AWP reported by Baxter in the 2001 *Red Book*.

Drug in Lowest Dosage Form	Baxter's 2001 Red Book AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Dextrose	\$928.51	\$2.25	\$926.26	41,167%
Dextrose Sodium Chloride	\$357.69	\$2.93	\$354.76	12,108%
Sodium Chloride	\$928.51	\$1.71	\$926.80	54,199%
Factor VIII	\$1.28	\$.92	\$.36	39%

(P006299-006316).

#### 6. Evidence Concerning Gammagard S/D (immune globulin solution)

281. Baxter admittedly manipulated the AWP for Gammagard S/D. In 1996, Baxter distributed a memo providing "[t]he deliberate manipulation of AWP or WAC prices is a problem that we need to address. The spread between acquisition cost and AWP/WAC is a direct profit for customers, and is being used to increase product positioning in the market by certain manufacturers." Immediately below this text is a handwritten note reading "[w]ill raise AWP for GG/SD by 15%." (BAX MDL 0012778) (Highly Confidential).

282. According to Baxter's own documents, the published AWP's for Gammagard S/D were higher than the actual prices provided to wholesalers. In a customer announcement dated September 24, 1996, Baxter increased the AWP for one particular dosage of Gammagard S/D from \$640.71 to \$737.00, and the WAC from \$365.00 to \$420.00. The difference between the new AWP and the new WAC (\$317.00) constituted a 43% spread. (BAX MDL 005366) (Highly Confidential).

#### 7. Inflated AWP's From Baxter's Price Lists

283. In response to government subpoenas, Baxter produced numerous price lists setting forth spreads between AWP's and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Baxter has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the



published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Tables 1 and 2 are a number of those drugs (not already referenced above) with spreads between the AWP's and direct prices. Table 1 is an analysis of certain dosages of Baxter drugs from a document entitled "Baxter Healthcare Corporation Intravenous and Irrigation Solution Products Report" (BAX MDL 0003428-46) (Highly Confidential)).

**Table 1**

<b>Drug</b>	<b>AWP</b>	<b>DP</b>	<b>Difference</b>	<b>% Spread</b>
Ringers	10.84	6.34	4.50	71%
Lactated Ringers	12.36	7.43	4.93	66%
Plasma-lyte 148	15.67	10.85	4.82	44%
5% Travert and electrolyte no. 2	16.39	11.30	5.09	45%
6% Gentran75	73.46	33.19	40.27	121%
Sterile Water	9.97	6.15	3.82	62%
Sodium Lactate	17.98	11.11	6.87	62%
Osmitol	70.28	35.12	35.16	100%
Gentamycin	10.78	7.25	3.53	49%
Metronidazole injection	15.34	7.85	7.49	95%
Rocephin	40.18	32.67	7.51	23%
Nitroglycerin	17.37	9.82	7.55	77%
Potassium Chloride Injection	14.63	10.16	4.47	44%
Dopamine	19.30	13.40	5.90	44%
Lidocaine	22.74	13.48	9.26	67%
Heparin	9.94	6.49	3.45	53%
Theophylline	11.45	7.81	3.64	47%
Glycine for Irrigation	32.87	19.70	13.17	67%
Tis-U-Sol	22.73	11.36	11.37	100%
Acetic Acid	20.70	10.91	9.79	90%
Irrigating Solution G	16.67	11.04	5.63	51%
Balanced Salt Solution	28.76	15.00	13.76	92%
Sodium Bicarbonate	39.23	16.36	22.87	140%

284. Table 2 is an analysis of certain dosages of Baxter drugs from a document entitled "IV Nutrition Products" (BAX MDL 0003421-26) (Highly Confidential).

**Table 2**

<b>Drug</b>	<b>AWP</b>	<b>DP</b>	<b>Difference</b>	<b>% Spread</b>
Novamine Injection	95.14	51.48	43.66	85%
Travasol	83.44	40.21	43.23	108%
RenAmin Injection	75.00	48.00	27.00	56%



Aminess Essential Amino Acid	107.35	66.00	41.35	63%
BranchAmin Injection	93.60	60.00	33.60	56%

#### **8. Baxter Provided Free Goods and Other Incentives**

13. Baxter also provided physicians with free goods with the understanding that physicians would bill for those goods, in violation of federal law. Billing for free goods was a way for physicians to obtain greater profit at the expense of the Class. Baxter's fraudulent use of free goods aimed at increasing market share is evidenced by an internal memorandum from a Baxter contract administrator to certain field sales managers encouraging the distribution by U.S. mail or otherwise of free product to achieve overall price reduction:

BAXTER: "The attached notice from Quantum Headquarters was sent on April 10th to all their centers regarding the reduction on Recombinate pricing. Please note that they want to continue to be invoiced at the \$.81 price. They have requested that we send them free product every quarter calculated by looking at the number of units purchased in that quarter and the \$.13 reduction in price . . . free product given to achieve overall price reduction."

Letter from Stark, Committee on Ways and Means to Holman, Pres. Pharmaceutical Research and Manufacturers of America, Sept. 28, 2002 (P0075410-44).

285. As set forth above, Baxter's scheme to inflate its reported AWP's, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

#### **F. Bayer**

286. Bayer engages in an organization-wide and deliberate scheme to inflate AWP's. Bayer has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below. The specific drugs of Bayer for which relief is sought in this case are set forth in Appendix A, and are set forth below:





Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Uses
BAYER	Cipro	ciprofloxacin or ciprofloxacin hcl	Antibiotic Agent (Anti-Infective Agent) Used in the treatment of various bacterial infections, including anthrax
	Cipro XR	ciprofloxacin hcl-ciprofloxacin betaine	Antibiotic Agent (Anti-Infective Agent) Used in the treatment of various bacterial infections, including anthrax
	DTIC-Dome	dacarbazine	Antineoplastic Used in the treatment of melanoma and Hodgkin's disease
	Gamimune N	immune globulin (human) iv	Immunizing Agent Used as maintenance therapy in patients with compromised immune systems
	Koate-HP	antihemophilic factor (human)	Antihemophilic Factor (Blood Modifier) Used to increase blood clotting and decrease bleeding episodes
	Kogenate	antihemophilic factor (recombinant)	Antihemophilic Factor (Blood Modifier) Used to increase blood clotting and decrease bleeding episodes
	Mithracin	plicamycin	Antineoplastic; Antihypercalcemic Agent Used in the treatment of various forms of cancer

# **1. Bayer Has Been the Target of Government Investigations**

287. In connection with its scheme to inflate AWP's, Bayer has been investigated by the Department of Justice, Department of Health and Human Services, Office of Inspector General, and the Commonwealth of Massachusetts. Bayer agreed to settle claims asserted by the United States government and 47 states arising from its fraudulent pricing and marketing practices. According to the DOJ's January 23, 2001 press release:

The government's investigation of the allegations...revealed that [Bayer] beginning in the early 1990s, falsely inflated the reported drug prices – referred to by the industry as the Average Wholesale Price (AWP), the Direct Price and the Wholesale Acquisition Cost – used by state governments to set reimbursement rates for the Medicaid program. By setting an extremely high AWP and, subsequently, selling drugs at a dramatic discount, Bayer induced physicians to purchase its products rather than those of competitors by enabling doctors to profit tremendously from reimbursement paid to them by the government.



The Bayer AWP's at issue in the investigation involved Bayer's biologic products such as Kogenate, Koate-HP, and Gamimmune, which are widely used in treating hemophilia and immune deficiency diseases. The investigation further revealed that the practice in which Bayer selectively engaged, commonly referred to as "marketing the spread," also had the effect of causing other drug companies to inflate their AWP's.

"Bayer Corporation Settlement on Medicaid Drug Prices" (P011236-011237).

288. As part of its settlement of government claims in 2000, Bayer is required, under the terms of a corporate integrity agreement, to provide state governments and the federal government with the average selling prices of its drugs – a price which accounts for all discounts, free samples, rebates and all other price concessions provided by Bayer to any relevant purchaser that result in a reduction of the ultimate cost to Bayer's customers.

289. In April 2003, Bayer also agreed to pay the government \$251.6 million in civil penalties for violating the Federal Prescription Drug Marketing Act for alleged overcharges involving its antibiotic Cipro and its high blood pressure drug Adalat.

## **2. Bayer Controls the Published AWP for Its Products**

290. Bayer has controlled and set the AWP's for its pharmaceutical products through direct communications with industry compendia during the Class Period. In one internal marketing memorandum, Bayer stated:

I would like to formally request that you contact Redbook and request an AWP change for all sizes (670-20, 670-30, 670-50) of Kogenate from \$1.18 per IU to \$1.24 per IU to match Baxter's increase. I have attached a letter from Baxter to Redbook outlining their price change request. (Prior to making the change in AWP for Kogenate, please confirm with Redbook that Baxter has indeed initiated a price change.)

(BAY005278) (Highly Confidential).

## **3. Bayer's AWP Manipulation Benefited Providers at the Expense of the Class**

291. As detailed in a September 28, 2000 letter from Representative Stark to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, internal Bayer



documents reveal Bayer knowingly participated and directed the scheme to artificially inflate the AWP for its products and to market the spread:

BAYER: "Chris, if Baxter has increased their AWP then we must do the same. Many of the Homecare companies are paid based on a discount from AWP. If we are lowed [sic] than Baxter then the return will be lower to the HHC. It is a very simple process to increase our AWP, and can be done overnight."

(P007549.)

292. Tom Bliley, in a letter dated September 25, 2000 to the Health Care Financing Administration, analyzed drug sales in Florida and noted that sales of Bayer's WhinRho "skyrocketed" when competitors reduced their spreads but Bayer did not.

#### 4. Specific Bayer AWP Documented by the DOJ

293. In a report published by the DHHS, the DOJ documented at least 10 instances where the published AWP for various dosages of two drugs manufactured by Bayer were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the two drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Abbott in the 2001 *Red Book*.

Drug	Bayer's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Immune Globulin	\$450.00	\$362.50	\$87.50	24%
Factor VIII	\$0.92	\$0.42	\$0.50	119%

(AB-00-86 (P006299-006316)).

294. In a DHHS OIG report (*see* OEI-03-00-00310 (P006398-006424)), the government also discovered that the AWP for all immune globulin pharmaceuticals (of a dosage of 5g), including Bayer's Gamimune® (Bayer was one of five manufacturers of the dosage listed in the 1997 *Red Book*), were over inflated by an average spread of 32.21%.



295. According to the government's settlement with Bayer arising out of Bayer's fraudulent pricing and marketing practices, the Bayer AWP's at issue in the investigation (and ultimately settled) include the AWP's for Kogenate.

**5. Inflated AWP's From Bayer's Price Lists**

296. According to Bayer's own documents, the published AWP's for its drugs were higher than the actual prices provided to wholesalers. In response to government subpoenas, Bayer produced numerous price lists setting forth spreads between AWP's and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Bayer has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers.

**6. Bayer Provided Free Goods and Other Incentives**

297. In addition to marketing the spread, Bayer has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, Bayer provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

298. Evidence of these practices is found in an October 1, 1996 Bayer internal memorandum addressing volume sales opportunities for the pharmaceutical Kogenate®:

BAYER: "I have been told that our present Kogenate price, \$.66 is the highest price that Quantum is paying for recombinant factor VIII. In order to sell the additional 12mm/u we will need a lower price. I suggest a price of \$.60 to \$.62 to secure this volume. From Quantum's stand [sic] point, a price off invoice, is the most desirable. We could calculate our offer in the form of a marketing grant, a special educational grant, payment for specific data gathering regarding Hemophilia treatment, or anything else that will produce the same dollar benefit to Quantum Health Resources."



299. As set forth above, Bayer's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

300. Bayer routinely offered its customers off-invoice discounts as one feature of its standard contracts. (BAYM002428).

#### **7. Bayer Concealed Its AWP Manipulation**

301. Bayer deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. Bayer routinely required that its customers keep secret the prices they were being charged for Bayer drugs. (BAYM000913, BAYM002436).

#### **G. The Boehringer Group**

302. The Boehringer Group engages in an organization-wide and deliberate scheme to inflate AWP's. The Boehringer Group has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below. The specific drugs of The Boehringer Group for which relief is sought in this case are set forth in Appendix A and are identified below:

Manufacturer	Brand Name (Trade Name)	Generic Name	Therapeutic Category/Usage
BOEHRINGER GROUP (Boehringer, Ben Venue, Bedford and Roxane)	Viramune	nevirapine	Antiviral Agent (Anti-Infective Agent) Used in the treatment of HIV infection
		acyclovir sodium	Anti-Infective Agent Used in the treatment of herpes infections
		amikacin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat respiratory tract, urinary tract, bone, skin and soft tissue infections
		cytarabine	Antineoplastic Used to treat leukemia and non-Hodgkin's lymphoma
		doxorubicin hydrochloride	Antineoplastic Used in the treatment of ovarian cancer and AIDS-related Kaposi's sarcoma



Trade Name	Brand Name (NDC)	Generic Name	Therapeutic Category/Use
		etoposide	Mitotic Inhibitor (Antineoplastic) Used in the treatment of testicular neoplasm and small cell cancer of the lung
		leucovorin calcium	Antianemic Agent (Blood Modifier) Used in the treatment of anemia
		methotrexate sodium	Antineoplastic Used in the treatment of various forms of cancer
		mitomycin	Antineoplastic Used in the treatment of various forms of cancer
		vinblastine	Antineoplastic Used in the treatment of various forms of cancer, including lymphoma and breast cancer
		vinblastine sulfate	Antineoplastic Used in the treatment of various forms of cancer, including lymphoma and breast cancer

## 1. The Boehringer Group Has Been the Target of Government Investigations

303. In connection with its scheme to inflate AWP's, The Boehringer Group has been investigated by the Department of Justice, the Department of Health and Human Services Office of Inspector General, the Committee on Commerce of the House of Representatives, and the Nevada Attorney General.

## 2. The Boehringer Group Controls the Published AWP for Its Products

304. The Boehringer Group has controlled and set the AWP's for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, a September 27, 1996 document entitled "*Red Book* Product Listing Verification" required Defendant to sign each page that contained a list of The Boehringer Group's products, NDC numbers, AWP's, WAC's and price effective dates. (MDL BV 000799). Similarly, a *Red Book* New Product Information Form dated November 25, 1996 was completed by Bedford for





the drug Ketamine Hydrochloride Injection USP and required Bedford to fill in the AWP and WAC for the product (which it did). (MDL BV 000807).

305. Despite its actual verification of the AWP's in the *Red Book*, The Boehringer Group claims that it does not set "AWPs" but nonetheless agrees that the "terms 'average' and 'wholesale' are the standard dictionary definitions." In a letter dated August 20, 1999 to the Chairman of the Committee on Commerce regarding "Response to Request for Pricing Information, July 19, 1999" ("Bedford's AWP Response"), counsel for Bedford Laboratories stated as follows:

***Please provide all definitions of AWP used by your company since January 1, 1996 for the purpose of determining the reimbursement price for Medicare-covered drugs, and all records relating to those definitions. In particular, please provide the specific definitions you apply to the terms "average" and "wholesale."***

***Answer:*** The term "AWP", which we interpret as meaning Average Wholesale Price, is not used by Bedford Laboratories in pricing any of its products. Moreover, Bedford has not and does not take into account the "reimbursement price for Medicare-covered drugs" in pricing any of its products. Rather than use AWP, Bedford established a Hospital Price List for its products. The Hospital Price List refers to the price a customer without a contract, who is not a wholesaler or distributor, would pay for Bedford's products. It also refers to a suggested price that a wholesaler charges its customers. This terminology is used because the majority of Bedford's customers, particularly for drugs such as Leucovorin, are hospitals.

The pharmaceutical reporting services, such as Redbook, independently identify Bedford's Hospital Price List as AWP. The prices Bedford charges its wholesale customers are referred to at Bedford as Wholesale Price Lists, which are identical for all of Bedford's wholesale customers. These prices are identified by the pharmaceutical reporting services as Wholesale Acquisition Cost ("WAC"). ***Given its pricing terminology and practices, Bedford's definitions of the terms "average" and "wholesale" are the standard dictionary definitions."***

(MDL BV 001941-1944, at 1941-1942) (Confidential) (emphasis added).



306. Notwithstanding its attempt to distance itself from its published AWP, The Boehringer Group effectively ratified the AWP set by its predecessors. In Bedford's AWP Response, counsel responded:

. . . Bedford performs no AWP calculation for Leucovorin, 50 mg and did not do so during calendar year 1998. . . . This price was established by Chiron Therapeutics, which prior to May, 1996, had the marketing responsibilities for this product. Bedford took over those responsibilities in May of 1996 and continued the price established by Chiron. Prior to that time, Ben Venue, Bedford's parent, only manufactured this product. For that reason, Bedford is not aware of how Chiron originally priced this product.

(MDL BV 001941-1944, at 1942) (Confidential) (emphasis added).

307. Of course, depending on which government entity was performing the investigation and the date of the government's inquiries, The Boehringer Group's "definition" of AWP changed. By November 2, 1999, Bedford told the Committee on Commerce that it understood AWP to be tied to "the manufacturer's suggested prices to customers of its customers." (MDL BV 006761-65, at 6763).

308. In a letter dated June 5, 2000 to the Nevada Attorney General regarding the Attorney General's inquiries about Bedford's AWP, Bedford responded in pertinent part:

**1. Identify what Bedford represents to be its understanding of the meaning "AWP."**

Answer: Bedford's understanding of AWP, derived from its experience in the industry, is that it is a suggested price identified by pharmaceutical companies as the price a wholesaler may wish to charge its customers for pharmaceutical products. Bedford has always viewed AWP as a suggested 'retail' price to the customers of wholesalers and not as an acquisition cost to wholesalers.

**2. Does Bedford report AWP to First Databank for all its products? With what frequency? How is that information communicated?**

Answer: Bedford does not use the term AWP in its business, *except as a semantical concession* to those who, like the price reporting services, have reported Bedford's Hospital List Price ("HLP") as an AWP. Upon request by FDB, Bedford provides its



price lists, which consist of the HLPs and Wholesale List Prices (“WLPs”) for its products. \*\*\*\*

Bedford reports this information, usually by facsimile, at least once a year, and more frequently upon request by FDB.

(MDL BV 002071-73, at 2072) (Confidential) (emphasis added).

309. In fact, even armed with the knowledge that industry compendia use Bedford’s HLPs as AWP, Bedford admits that HLPs do not accurately reflect the AWP for its drugs:

As indicated above, Bedford does not communicate AWP for its products. However, it is aware that pharmaceutical price reporting services have chosen to report Bedford’s HLP as AWP. Bedford has always reported its HLP accurately. *These list prices are not averages of the wholesale prices for Bedford’s products.*

(MDL BV 002071-73, at 2073) (emphasis added).

310. In practice, Bedford did in fact acknowledge that its HLPs should be used as AWP in the industry compendia. For example, a June 17, 1996 fax cover sheet from Bedford to Medispan states: “[S]ee corrections noted for select products on the AWP cost!” (MDL BV 000770) (Confidential). Attached to this cover sheet is Bedford’s Hospital Price List dated May 1, 1996 in which certain prices are crossed out and replaced with typewritten prices. (MDL BV 000771-780) (Confidential). Similar cover sheets with the same notation and the same price lists were also sent to First Data Bank (MDL BV 000774-780, MDL BV 000781-785) (Confidential) (“[S]ee corrections made on select products for the AWP!”) and *Red Book* (MDL BV 000793-95) (Confidential) (“Corrections made on the AWP for select products!”).

### 3. Specific Boehringer AWP Documented by the DOJ

311. In a report published by the DHHS, the DOJ documented at least 32 instances where the published AWP for various dosages of nine drugs manufactured by The Boehringer Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the nine drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ’s determination of an accurate AWP for



that particular dosage, based upon wholesalers' price lists, with the AWP reported by The Boehringer Group in the 2001 *Red Book*.

Drug	The Boehringer Group's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Acyclovir Sodium	\$ 528.00	\$ 207.00	\$ 321.00	155%
Amikacin Sulfate	\$ 437.50	\$ 65.33	\$ 372.17	570%
Mitomycin	\$ 128.05	\$ 51.83	\$ 76.22	147%
Cytarabine	\$ 62.50	\$ 3.55	\$ 58.95	1,661%
Doxorubicin HCL	\$ 945.98	\$ 139.75	\$ 806.23	577%
Etoposide	\$ 110.00	\$ 8.45	\$ 101.55	1,202%
Leucovorin Calcium	\$ 184.40	\$ 2.76	\$ 181.64	6,581%
Methotrexate Sodium	\$ 68.80	\$ 2.63	\$ 66.17	2,516%
Vinblastine Sulfate	\$ 212.50	\$ 8.19	\$ 204.31	2,495%

#### 4. Inflated Boehringer Group AWP's From Bedford's Price Lists

312. According to Bedford's own documents, the published AWP's for the drugs listed above by the DOJ were, in fact, higher than the actual prices provided to wholesalers. In response to government subpoenas, Bedford produced several price lists setting forth spreads between AWP's and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Bedford has consistently offered the above drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. (MDL BV 000799-806).

313. As set forth above, The Boehringer Group's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

#### H. B. Braun

314. B. Braun engages in an organization-wide and deliberate scheme to inflate AWP's. B. Braun has stated fraudulent AWP's for all or almost all of its drugs, including those set forth



below. The specific drugs of B. Braun for which relief is sought in this case are set forth in Appendix A and identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Uses
B. BRAUN		dextrose	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids
		dextrose in lactated ringers	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids
		dextrose w/ sodium chloride	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids
		heparin sodium (porcine) in d5w	Blood Modifier Used to treat and prevent thrombosis and pulmonary embolism
		sodium chloride	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion
		sodium chloride (gu irrigant)	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion

# 1. B. Braun Has Been the Target of Government Investigations

315. In connection with its scheme to inflate AWP's, B. Braun has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, and the Attorney General for the State of California.

## 2. B. Braun's Understanding of AWP

316. Undated notes made in conjunction with a meeting held to address a customer's concerns about B. Braun's decision to increase AWP's for a number of drugs reveals B. Braun's understanding of AWP's:

Let Rob know that most products are already (AWP's) above wholesaler prices. Make him understand that AWP's are based on not what prices they buy it at but at what price they . . . . This



doesn't matter as for as setting AWP's it is not what the wholesaler sells the products for that set the AWP price (average sell prices).

B. Braun's documents prove that it knew that customers – and members of the Class – understood AWP's to be related to average wholesale prices. (BBMDL 001907) (Highly Confidential).

### 3. B. Braun Controls the Published AWP for Its Products

317. B. Braun has controlled and set the AWP's for its pharmaceutical products through direct communications with industry compendia during the Class Period.

a. A September 11, 1995 McGaw (acquired by B. Braun in 1997) internal memorandum addresses the company's recognition of its ability to control the published AWP:

Below I have listed all data base companies the specific percentage mark-up that they apply to our "list" prices:

First Data Bank	20%
Medispan	25%
Redbook	Whatever we want them to publish
Facts & Comparisons	Information on our products should be submitted to this company although they do not publish pricing, only clinical data

Connie, when we submit our list and AWP prices to these companies this year, let's submit a mark-up of 25% above our list prices to all companies so it will be consistent.

(BBMDL 000013) (Highly Confidential).

b. Notes from an October 1994 telephone conversation between a representative of *Red Book* and McGaw provide further proof that B. Braun understood it could unilaterally control its AWP's:

Spoke to Roni Lane at Redbook. She did not know why Baxter not listed in OTC section. She said we can send her whatever price for AWP we want and she will have it published.[ ] If we increase AWP prices we can send her only AWP to have published ad not list so spread between the 2 won't show. No one regulates pricing





this is up to the mfg. Co. and it is option that mfg. Publish theirs,  
not a requirement.

(BBMDL 013372) (Highly Confidential).

**4. B. Braun's AWP Manipulation Benefited Providers at the Expense of the Class**

318. The purpose of B. Braun's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class. Braun understood, as reflected in a June 15, 1992 memorandum, that a higher AWP was "advantageous with payors who reimburse based on a cost plus arrangement." (BBMDL 008056) (Highly Confidential).

319. As evidenced by a September 18, 1996 e-mail, B. Braun recognized that manipulating AWP's to meet its competitors was "scandalous," "unethical" and "fraudulent":

I'm writing to you because of a potential problem for McGaw and a potentially larger problem for IVAX. It has to do with the method in which products are sold in our industry at a low actual price, and the wholesaler (our customer) bills Medicare for an arbitrary "average wholesale price." These prices are published in compendia such as Red Book and Blue Book.

I'm wondering if you saw the article in *Barron's* on June 10, 1996. This issue is described in great detail including the fact that the Justice Department is looking into the issue and the Inspector General of Medicare is investigating these practices.

I have held up authorizing the continuation of this practice at McGaw for quite a few months, but they're most anxious to continue the process as our sales are suffering. According to the article, some say that it is not illegal, but it is unethical. I am concerned that McGaw will no sooner increase its average wholesale prices to meet its competitors when the entire industry is going to get slammed for what may be perceived as scandalous, or worse, fraudulent practice of reimbursement.

(BBMDL 000011) (Highly Confidential).

320. Despite discussing and memorializing its concerns, B. Braun promptly proceeded to manipulate its AWP's and market the spread in an effort to match the competition.



a. In an internal memorandum dated December 20, 1996, a B. Braun employee states:

I evaluated each McGaw AWP against Baxter's and Abbott's and individually determined which AWP's should be increased. . . . In general, I raised the McGaw AWP's to make them equivalent to Baxter.

(BBMDL 009658) (Highly Confidential).

b. A second memorandum, created in October of 1997 reveals that B. Braun subsequently performed an analysis to "assure that McGaw AWP's are in line with Baxter/Abbott AWP's on competitive products." (BBMDL 009763) (Highly Confidential). In fact, an October 17, 1997 B. Braun memorandum reveals that the company increased 54 separate AWP's following a review of 200 drugs to "make them equivalent to both Baxter and Abbott." (BBMDL 001891) (Highly Confidential). B. Braun increased the AWP's of 29 drugs in 1996 for the same reason. (BBMDL 009658) (Highly Confidential).

321. B. Braun, through its employees and agents, also provided free samples of its drugs, and purported educational grants, to providers. The free samples and educational grants would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class.

322. In an October 30, 1998 memorandum addressing pricing strategies for its drug ProcalAmine, in lieu of a price reduction, B. Braun directs personnel to offer customers "something of value instead – for example, give them an educational grant, or sponsor a speaker[.]" The same memorandum also suggests that B. Braun employees might offer a "free case for every so many purchased" to match competitors' prices "without lowering" the price of its drug. (BBMDL 002088) (Highly Confidential).

##### **5. Specific B. Braun AWP's Documented by the DOJ**

323. In a report published by the DHHS (the "DHHS Report"), the DOJ documented at least 23 instances where the published AWP's for various dosages of 3 drugs manufactured by



B. Braun were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 3 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by B. Braun in the 2001 *Red Book*.

Drug	B. Braun's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Spread
Dextrose	\$11.28	\$1.61	\$9.67	601%
Dextrose Sodium Chloride	\$11.34	\$1.89	\$9.45	500%
Sodium Chloride	\$11.33	\$1.49	\$9.84	660%

#### 6. Inflated AWP's From B. Braun Price Lists

324. In response to government subpoenas, B. Braun produced numerous price lists setting forth spreads between AWP's and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that B. Braun has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Table 1 are a number of those drugs (not already referenced above) and the substantial spread offered to a particular B. Braun customer.

325. Table 1 is an analysis of certain dosages of B. Braun drugs from a document entitled "PHARMCO." (BBMDL 011831) (Highly Confidential)).

**Table 1**

Drug	Gerimed Unit Price	AWP	\$ Diff AWP	% Spread
Intralipid	\$6.75	\$57.87	\$51.12	757%
Lactated Ringers 1000	\$1.02	\$11.87	\$10.85	1063%
Travasol	\$6.05	\$82.34	\$76.29	1260%



326. As set forth above, B. Braun's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

**I. The BMS Group (Bristol-Myers, OTN and Apoteco)**

327. The BMS Group has engaged in an ongoing deliberate scheme to inflate AWP's. The specific drugs for which relief is sought in this case are identified in Appendix A and are as follows:

Manufacturer	Brand Name (If Applicable)	Generic Name	Therapeutic Category/Usage
BMS GROUP (Bristol-Myers, OTN and Apoteco)	Avapro	irbesartan	Antihypertensive Agent Used to treat hypertension
	Blenoxane	bleomycin sulfate	Antineoplastic Used in the treatment of various forms of cancer
	Buspar	bupirone hcl	Antianxiety Agent (Psychotherapeutic Agent) Used to treat certain anxiety disorders or to relieve the symptoms of anxiety
	Carboplatin	paraplatin	Antineoplastic Used to treat cancer of the ovaries
	Cefzil	cefprozil	Antibacterial Agent (Anti-Infective Agent) Used in the treatment of infections caused by bacteria
	Coumadin	warfarin sodium	Anticoagulant (Blood Modifier) Used to promote clotting
	Cytosan	cyclophosphamide	Antineoplastic Used in the treatment of various forms of cancer
	Etopophos	etoposide phosphate	Antineoplastic Used to treat cancer of the testicles and certain types of lung cancer
	Glucophage	meformin hcl	Antihyperglycemic Agent Used to treat a type 2 diabetes mellitus.
	Monopril	fosinopril sodium	Antihypertensive Agent; Vasodilator (Cardiovascular Agent) Used to treat hypertension
	Monopril HCT	fosinopril sodium & hydrochloro-thiazide	ACE Inhibitor (Cardiovascular Agent) Used in the treatment of hypertension and congestive heart failure
	Plavix	clopidogrel bisulfate	Antithrombotic Agent Used to lessen the chance of heart attack or stroke



Manufacturer	Brand Name (if applicable)	Generic Name	Indications/Category/Uses
	Rubex	doxorubicin hcl	Antineoplastic Used in the treatment of various forms of cancer
	Serzone	nefazodone hcl	Antidepressant (Psychotherapeutic Agent) Used to treat mental depression
	Taxol	paclitaxel	Antineoplastic Used in the treatment of various forms of cancer
	Tequin	gatifloxacin	Antibacterial Agent (Anti-Infective Agent) Used to treat bacterial infections
	Vepesid	etoposide	Antineoplastic Used to treat cancer of the testicles and certain types of lung cancer
	Videx EC	didanosine	Antiviral Agent (Anti-Infective Agent) Used in the treatment of HIV infection
		amikacin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat respiratory tract, urinary tract, bone, skin and soft tissue infections
		amphotercin b	Antifungal Agent (Anti-Infective Agent) Used to help the body overcome serious fungus infections

# **1. The BMS Group Has Been the Target of Government Investigations**

328. In connection with its scheme to inflate AWP's, BMS has been investigated by the United States Department of Justice, Commonwealth of Massachusetts, Office of Inspector General of the U.S. Department of Health and Human Services, Attorney General for the State of Texas, State of California Department of Justice Office of the Attorney General, State of California Department of Justice, Bureau of Medi-Cal Fraud and Elder Abuse, and the U.S. House of Representatives, Committee on Commerce. Defendant Apothecon has been investigated in connection with its scheme to inflate AWP's by at least the Office of Medicare Fraud and Elder Abuse, Office of Attorney General, State of Texas.

329. These investigations confirm that BMS engaged in an ongoing deliberate scheme to inflate AWP's. For example, by letter dated February 27, 2001 to BMS, Rep. Stark outlined numerous examples of illegal practices by BMS. Referring to a letter from Denis Kaszuba, a



senior pricing analyst at BMS to Medispan, dated August 10, 1992 (BMSAWP/0011247), Rep.

Stark noted:

Bristol has control over the AWP, DP, and WACs published for its drugs and directs national publishers to change their prices. Bristol directed a national publisher of drug prices to increase all of Bristol's AWP for oncology drugs by multiplying Bristol's supplied direct prices by a 25% factor rather than the previous 20.5% factor . . . The increase in the AWP created a spread that, in itself, provided a financial kickback to oncologists for prescribing Bristol's cancer drugs.

330. In the same letter, Rep. Stark noted:

The evidence clearly shows that Bristol has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Bristol manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs where the arranging of a financial benefit or inducement would influence the decisions of healthcare providers submitting the Medicare and Medicaid claims.

## 2. The BMS Group Controls the Published AWP for Its Products

331. The BMS Group has controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia during the Class Period. In one BMS document, Denise Kaszuba, a senior BMS Group pricing analyst, instructed the *Red Book* that:

Effective immediately, Bristol-Myers Oncology Division products factor used in determining the AWP should be changed from 20.5% to 25%. This change should not effect [*sic*] any other business unit of Bristol-Myers Squibb Company.

332. Other internal documents clearly indicate that BMS had direct control over the spread between its states wholesale price and the published AWP. A BMS office dispatch dated September 9, 1992 notes the need for a mark up of the AWP over the state wholesale price. "After reviewing the results of the wholesaler survey performed by Bristol Oncology . . we have determined that for those items with a labeler 0003, we will use a 1.25 mark-up and for those





items with the labeler 00015, we will use a 1.20 mark-up. We noticed too, that FDB and Redbook use a 1.20 for everything.” (BMSAWP/0011246).

**3. BMS’s AWP Manipulation Benefited Providers at the Expense of the Class**

333. BMS was well aware that providers and other purchasers of its drugs were using the spread to determine whether to purchase its drugs. Indeed, BMS was aware of and tracked the prices and AWP’s of its competitors in order to remain competitive. In an internal BMS memorandum, BMS identifies its competitors who sell etoposide (Gensia, Pharmacia, Abbott, Chiron, Ben Venue, Immunex and Astra) and their corresponding list price and AWP’s. (BMS3CA/000128).

334. BMS created AWP competitor analyses that tracked the AWP’s of its competitors’ relevant drugs, and used that data internally to propose suggested AWP’s for BMS drugs. One such competitor analysis set forth the competitor AWP’s for Atenolol with chlorthalidone and provided an “Apothecon suggested AWP” for each dosage. (BMS3CA/000648)

335. BMS clearly believed that the maintenance of a spread on its drugs was important in gaining and maintaining market share. In an internal BMS document, concerning its drug Vepacid (etoposide), BMS noted:

The Etopophos product file is significantly superior to that of etoposide injection . . . . Currently, physician practice can take advantage of the growing disparity between Vepesid’s list price (and, subsequently, the Average Wholesale Price) and the actual acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physician’s financial incentive for selecting the brand is largely diminished.

**4. Specific BMS AWP’s Documented by the DOJ**

336. In a report published by the DHHS, the DOJ documented numerous instances where the published AWP’s for various dosages of five (5) drugs manufactured by the BMS Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the BMS Group drugs identified by the DOJ and the spread associated with one



particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by the BMS Group in the 2001 *Red Book*.

Drug	Manufacturer	BMS's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Amikacin Sulfate	Apothecon	\$32.89	\$17.31	\$15.58	90%
Amphotercin B	Apothecon	\$17.84	\$6.20	\$11.64	188%
Bleomycin Sulfate	BMS	\$609.20	\$509.29	\$99.91	20%
Cyclophosphamide	BMS	\$102.89	\$45.83	\$57.06	125%
Etoposide (Vepesid)	BMS	\$136.49	\$34.30	\$102.19	298%

337. Other sources reveal additional evidence of fraudulent AWP's for drugs manufactured and marketed by the BMS Group:

#### 5. Other AWP's Related to VEPESID (etoposide)

338. The February 27, 2001 letter from Rep. Stark to BMS noted that as to BMS "... the manipulated discrepancies between [BMS's] inflated AWP's and DP's versus their true costs are staggering. For example, in the 2000 edition of the *Red Book*, Bristol reported an AWP of \$1296.64 for ... Vepesid (Etoposide) for injection ... while Bristol was actually offering to sell the exact same drug to [a large national group purchasing organization] for \$70.00." The difference noted by Rep. Stark represents a % 1,752 spread related to Vepesid.

#### 6. Other AWP's Related to Blenoxane

339. BMS internal documents reveal that in 1995, BMS set the *Red Book* AWP for Blenoxane at \$276.29. At the same time, BMS was selling Blenoxane to oncologists practicing in St. Petersburg, Florida for only \$224.22. In 1996, BMS increased its reported AWP for Blenoxane to \$291.49, while continuing to sell the drug to oncologist for \$224.27. In 1997, BMS falsely reported that it had increased the AWP of Blenoxane to \$304.60, when in reality, BMS had lowered the price to oncologists to \$155.00. In 1998, BMS again reported a false AWP for Blenoxane of \$304.60 while further reducing the actual price to oncologists to \$140.00.



## 7. The BMS Group Provided Free Goods and Other Incentives

340. As part of its scheme the BMS Group also used free drugs and other goods to encourage participation by physicians. Thus, for example, the BMS Group provided free Etopophos® to two Miami oncologists in exchange for their agreement to purchase other BMS Group cancer drugs. Similarly, other documents show that the BMS Group provided free Cytogards in order to create a lower-than-invoice cost to physicians that purchased other cancer drugs through OTN. (A Cytogard is a device that prevents spillage of intravenous administered treatments such as BMS's cancer drug Etopophos®.)

341. As set forth above, the BMS Group's scheme to inflate its reported AWP's, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

342. For example, in a report published by DHHS, the DOJ documented at least 12 instances where the published AWP's for drugs manufactured by the BMS Group were substantially higher than the actual prices listed by wholesalers.

343. The chart below sets forth five examples where the BMS Group deliberately inflated AWP's that it reported for BMS Group drugs. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by the BMS Group in the 2001 *Red Book*.

Drug	Manufacturer	BMS's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Amikacin Sulfate	Apothecon	\$32.89	\$17.31	\$15.58	90%
Amphotercin B	Apothecon	\$17.84	\$6.20	\$11.64	188%
Bleomycin Sulfate	BMS	\$609.20	\$509.29	\$99.91	20%
Cyclophosphamide	BMS	\$102.89	\$45.83	\$57.06	125%
Etoposide (Vepesid)	BMS	\$136.49	\$34.30	\$102.19	298%

344. In 1997, an OIG Report identified three other Medicare Part B drugs with inflated AWP's – which the 1997 *Red Book* indicates were manufactured only by the BMS Group at that



time: Paraplatin® (carboplatin), Rubet® (doxorubicin hydrochloride), and Taxol® (paclitaxel). Sales of these inflated drugs were substantial. For example, Paclitaxel generated \$941 million in revenue for the BMS Group in 1997, and Carboplatin generated \$702 million in revenue in 2001.

345. The government's investigation uncovered other drugs for which the BMS Group was stating a fraudulent AWP. Specifically:

- a. In the 2000 edition of the *Red Book*, BMS reported an AWP of \$1296.64 for Vepesid (Etoposide) for injection while BMS was actually offering to sell the exact same drug to a large customer for only \$70.00.
- b. From 1995 through 1998 the *Red Book* listed AWP for BMS' Blenoxane 15u increased from \$276.29 to \$304.60, while the actual cost to physicians declined from \$224.22 to \$140.00, resulting in a spread of \$164.60 in 1998

346. An internal BMS Group document shows that the AWP set by the BMS Group for its drugs bears no relation to an *actual* wholesale price, and is greater than the highest price actually paid by providers. More specifically, in a discussion about lowering Vepesid's AWP in order to create sales for Etopophos, the BMS Group stated that the "AWP for Vepesid would be reduced from its current level to the highest bid price currently in the marketplace."

347. BMS Group documents also reveal that physicians were making medical decisions based on how much profit they could make from the AWP manipulated spread. In considering provider choice between BMS drugs Etopophos® and Vepesid® (Etoposide), the BMS Group noted that:

The Etopophos product file is significantly superior to that of etoposide injection . . . . Currently, physician practice can take advantage of the growing disparity between Vepesid's list price (and, subsequently, the Average Wholesale Price) and the actual acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physician's financial incentive for selecting the brand is largely diminished.

348. While the BMS Group and other Defendants have placed the blame for setting published AWP's on the publications in which the AWP's are contained, another BMS Group



document demonstrates that publications reporting AWP's had no discretion to set AWP's, and instead published verbatim the prices reported by the BMS Group and other Defendants. In the document, Denise Kaszuba, a senior BMS Group pricing analyst, instructed the *Red Book* that:

Effective immediately, Bristol-Myers Oncology Division products factor used in determining the AWP should be changed from 20.5% to 25%. This change should not effect [sic] any other business unit of Bristol-Myers Squibb Company.

#### J. Dey

349. Dey engages in an organization-wide and deliberate scheme to inflate AWP's.

Dey has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below.

The specific drugs of Dey for which relief is sought in this case are set forth in Appendix A, and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
DEY		acetylcysteine	Mucolytic (Respiratory Agent: Diagnostic Aid) Used for certain lung conditions when increased amounts of mucus make breathing difficult
		albuterol or albuterol sulfate	Bronchodilator (Respiratory Agent) Used for relief of bronchospasm in asthma sufferers
		cromolyn sodium	Antiallergic and Mast Cell Stabilizer Used to help prevent or treat the symptoms of seasonal or chronic allergic rhinitis
		ipratropium bromide	Bronchodilator (Respiratory Agent) Used for relief of bronchospasm in asthma sufferers
		metaproterenol sulfate	Bronchodilator (Respiratory Agent) Used for relief of bronchospasm in asthma sufferers

#### 1. Dey Has Been the Target of Government Investigations

350. In connection with its scheme to inflate AWP's, Dey has been investigated by the United States Department of Justice, United States Department of Health and Human Services, Office of Inspector General, the United States District Attorney for the District of Massachusetts,



the Attorney General of the State of California, the Attorney General for the State of Texas, the Attorney General of the State of Connecticut, and the District Attorney for the County of Suffolk, New York State.

351. These investigations confirm that Dey has engaged in a deliberate scheme to inflate the published AWP for many of its drugs. For instance, Dey's spread for albuterol sulfate, a drug that constituted 37 % of Dey's income in 1998, drastically increased between 1992 and 1998. In 1992, Dey's *Red Book* AWP for albuterol sulfate (.083% concentration, 3 ml) was \$32.30. McKesson's wholesale price for the drug was \$25.45 (a spread of \$ 6.85 or 27%). By 1998, Dey's *Red Book* AWP for the same concentration/dose of albuterol sulfate had barely slipped to \$30.25, while McKesson's wholesale price had plummeted to \$10.00 (a spread of \$20.25 or 202%). See September 25, 2000 letter from U.S. Rep. Bliley to Nancy-Ann Min DeParle.

352. The federal government is not the only entity to uncover Dey's scheme to inflate AWP. The Attorneys General of Texas and West Virginia recently discovered that due to over inflated AWP, both state's Medicaid Programs have been defrauded by Dey for millions of dollars. Texas alleges that, between 1995 and 1999, it paid \$13.7 million for Dey's albuterol sulfate and ipratropium bromide, when it should have paid only \$8.7 million – an overcharge of \$5 million. West Virginia alleges that Dey and others manipulated the AWP to significantly overcharge state agencies and residents for several drugs, including albuterol, from at least 1995 through 2000.

353. In its own suit against Dey and other pharmaceutical manufacturers for AWP manipulation, the Attorney General for the State of Connecticut documented significant spreads between Dey's published AWP and actual wholesale prices for many of its drugs. Incorporated below are examples cited by the Connecticut Attorney General:





Drug	NDC #	Year	AWP	ACTUAL PRICE	SPREAD	% OVERCHARGE
ALBUTEROL	49502-0303-17	1996	\$21.70	\$3.25	\$18.45	488%
IPATROPIUM BORMIDE	49502-0685-03	2001	\$44.10	\$8.35	\$35.58	355%
IPATROPIUM BROMIDE	49502-0685-03	2000	\$44.10	\$11.45	\$32.65	239%
IPATROPIUM BROMIDE	49502-0685-03	1999	\$44.10	\$11.45	\$30.11	177%

## 2. Dey Controls the Published AWP for Its Products

354. Dey has controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia during the Class Period. Dey's own documents indicate that it initially set both the AWP and WAC for its products and also regularly approved subsequent AWP and WACs published by industry compendia. For example:

a. In a January 13, 1996 letter from Dey to First Data Bank, Day announced the availability of a new ipratropium bromide inhalation solution. The letter includes the following instructions to First Data Bank:

"Effective immediately, please update your database to reflect the introduction of this new DEY product as follows:

NDC/ Order Number	Description	Vial Size	Strength	Units per Ctn	Ctns per Case	AWP	WAC
49502-685-03	Ipratropium Bromide Inhalation Solution 2.0%	2.5ml	0.5mg/2.5ml	25	12	\$44.10	\$25.50
49502-685-60	Ipratropium Bromide Inhalation Solution 2.0%	2.5ml	0.5mg/2.5ml	60	12	\$105.60	\$60.90

(DL-CA00120) (Confidential)

b. In a 1998 worksheet produced by *Red Book* to Dey in order to verify its listings of Dey products, an employee of Dey went through each of the Dey products listed in the *Red Book* and approved each of the AWP and WACs for each of its products. Handwritten



comments on the document include the notation “9/11/98 – checked AWP & WAC pricing (backup attached)” (DL-CA 00080) (Confidential).

**3. Dey’s AWP Manipulation Benefited Providers at the Expense of the Class**

355. The purpose of Dey’s AWP manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries. This is clear from Dey’s own documents. For example:

a. Dey was aware that its customers were “spread shopping” and competed by increasing the spread to its customers. In an internal worksheet filled out by Dey in preparation for a bid of potential sales to one of its customers, Dey listed the current contract price of various products as well as a recommended new contract price. In the notes next to these figures the worksheet states, “This account needs AWP-40% or better to see profit due to the employer groups they serve. Have not made the switch to our product line due to the spread . . .” (DL-TX-0014029)

b. Competition between generic products produced by Dey was fierce and the spread was a major factor in this competition. In another similar bid price worksheet for a different customer, the corresponding notes state “cromolyn pricing is at AWP-40% and 35% respectively – bear in mind that we are competing with the branded spread and the generic perception of [sic] everything should be AWP-60%” (DL-TX-0014439)

356. This competition came at the expense of Plaintiffs and the Class whose payments were based on AWP. For instance, Albuterol sulfate, a multisource drug and one of Dey’s top selling products, was a focus of the federal government’s investigation into AWP inflation. OIG found that “Medicare’s reimbursement amount for albuterol was nearly six times higher than the median catalog price” and that “Medicare and its beneficiaries would save between \$226 million and \$245 million a year if albuterol were reimbursed at prices available to suppliers.” *See* “Excessive Medicare Reimbursement for Albuterol,” OEI-03-01-00410, March 2002.



357. The OIG determined that the Medicare-allowed amount for albuterol sulfate in 1996 was \$0.42. However the actual wholesale price was \$0.15, and the highest available wholesale price was \$0.21.

358. GAO also found that albuterol sulfate was one of a small number of products that accounted for a large portion of Medicare spending and volume. More specifically, albuterol sulfate ranked first in volume of units covered by Medicare, accounting for 65.8% of total units reimbursed. Furthermore, albuterol sulfate accounted for 6.3% of total Medicare spending, ranking fifth out of more than 400 covered drugs. *See* GAO Report to Congressional Committees, MEDICARE: Payments for Covered Outpatient Drugs Exceed Providers' Cost, Tables 1 and 2, pp. 7-8.

#### 4. Specific Dey AWP Documented by the DOJ

359. In a report published by the DHHS, the DOJ documented at least 15 instances where the published AWP for various dosages of 4 drugs manufactured by Dey were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each of the 4 drugs. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Dey in the 2001 *Red Book*.

Drug in Lowest Dosage Form	2001 <i>Red Book</i> AWP	DOJ Determined AWP	Difference	Percentage Spread
Acetylcysteine	\$59.88	\$25.80	\$34.08	132%
Albuterol Sulfate	\$30.25	\$9.17	\$21.08	230%
Cromolyn Sodium	\$42.00	\$23.01	\$18.99	82%
Metaproterenol Sulfate	\$30.75	\$11.29	\$19.46	172%

#### 5. Inflated Dey AWP From Dey's Price Lists

360. According to Dey's own documents, the published AWP for many of its own products were higher than the actual prices charged wholesalers and other intermediaries.



Table 1 below is excerpted from a pricing proposal by Dey to McKesson Drug Company, one of the county's largest wholesalers, dated December 20, 1995.

**Table 1**

Generic Name	Strength	Size	AWP	WAC	Suggested Sell Price	% Discount from WAC	% Spread
Acetylcysteine Solution	10%	4 mL	\$67.80	\$25.80	\$18.00	-40.0%	277%
Acetylcysteine Solution	10%	10 mL	\$40.26	\$15.27	\$13.50	-30.0%	198%
Acetylcysteine Solution	10%	30 mL	\$110.48	\$41.97	\$33.50	-35.0%	230%
Acetylcysteine Solution	20%	4 mL	\$81.36	\$31.08	\$21.50	-40.0%	278%
Acetylcysteine Solution	20%	10 mL	\$48.66	\$18.57	\$16.20	-30.0%	200%
Acetylcysteine Solution	20%	30 mL	\$133.43	\$50.64	\$39.90	-35.0%	234%
Acetylcysteine Solution	20%	100 mL	\$92.21	\$75.90	\$59.90	-40.0%	54%
Albuterol Sulfate Inhalation Soln.	0.083%	3 mL	\$30.25	\$14.50	\$12.00	-29.3%	152%
Albuterol Sulfate Inhalation Soln.	0.083%	3 mL	\$36.30	\$17.40	\$14.40	-29.3%	152%
Albuterol Sulfate Inhalation Soln.	0.083%	3 mL	\$72.60	\$34.50	\$28.80	-28.7%	152%
Cromolyn Sodium Inhalation, USP	20 mg/2ml	2 mL	\$42.00	\$34.20	\$29.00	-25.0%	45%
Cromolyn Sodium Inhalation, USP	20 mg/2ml	2 mL	\$84.00	\$66.00	\$58.00	-22.3%	45%
Metaproterenol Sulfate Inhalation Soln.	0.4%	2.5 mL	\$30.75	\$11.00	\$10.00	-21.5%	207%
Metaproterenol Sulfate Inhalation Soln.	0.6%	2.5 mL	\$30.75	\$11.00	\$10.00	-21.5%	207%
Sodium Chloride Solution	0.9%	3 mL	\$24.20	\$13.00	\$10.94	-32.7%	121%
Sodium Chloride Solution	0.9%	5mL	\$24.20	\$13.00	\$10.94	-32.7%	121%

(DL-TX 0011179)

#### 6. Dey Provided Free Goods and Other Incentives

361. In addition to marketing the spread, Dey has utilized other impermissible inducements to stimulate sales of its drugs without accounting for them in its WAC or AWP. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, Dey provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.



362. For example, in an announcement of a special incentive program to its customers to induce the purchase of its Ipratropium Bromide Inhalation solution, Dey sent its customers an offer sheet entitled “Profitability Enhancement For You” in which it stated “For every dollar of Dey Cromolyn Sodium unit-dose purchased, Dey will provide free goods of either: Coromolyn Sodium Inhalation Solution 0.02%, 2.5ml, at 1.0 times the rebate amount -OR- Ipratropium Bromide Inhalation Solution 0.02%, 2.5ml, when it launches, at a value of 1.5 times the rebate amount for Cromolyn.” (DL-TX-0004775).

**7. Dey Has Concealed Its AWP Manipulation**

15. In an effort to conceal the existence of a spread from end payors, Dey concealed the true wholesale prices of its drugs. For instance, in a handwritten memorandum to Dey’s pricing committee a potential pricing structure with a customer was discussed:

“I met with IPC to discuss our contract offer (illegible). . . Tom Konnelly (IPC) said he wanted to keep net pricing hidden from 3<sup>rd</sup> parties by increasing in the purchase price on our offer by 25%. IPC then requires a 25% rebate back to IPC. . . I have remarked the pricing. If this offer is accepted, the higher price will go into McKesson as a chargeback contract. Dey will then rebate IPC 25% on contract purchases on a quarterly basis. . .”

(DL-TX-0024844)

363. As set forth above, Dey’s scheme to inflate its reported AWP’s and market the resulting spread to increase the market share of its drugs and its use of other “off invoice” rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

**K. The Fujisawa Group (Fujisawa Pharmaceutical, Fujisawa Healthcare, Fujisawa USA)**

364. Fujisawa engages in an organization-wide and deliberate scheme to inflate AWP’s. Fujisawa has stated fraudulent AWP’s for all or almost all of its drugs, including those set forth below. The specific drugs of Fujisawa for which relief is sought in this case are set forth in Appendix A and are identified as follows:



Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category
FUJISAWA GROUP (Fujisawa Healthcare, Fujisawa Pharmaceutical and Fujisawa USA)	Aristocort	triamcinolone, triamcinolone diacetate or triamcinolone acetonide	Anti-Inflammatory, Steroidal; Used in the treatment of asthma
	Aristospan	triamcinolone hexacetonide	Anti-Inflammatory Agent, Steroidal Used to provide relief for inflamed areas of the body
	Cefizox	ceftizoxime sodium or ceftizoxime in d5w	Antibiotic Agent (Anti-Infective Agent) General antibiotic
	Cyclocort	amcinonide	Anti-Inflammatory Agent Used to treat inflammatory symptoms of skin disorders
	Lyphocin	vancomycin hydrochloride	Antibacterial Agent Used to treat infections in many different parts of the body
	Nebupent	pentamidine isothionate	Antiprotozoal Agent Used to try to prevent Pneumocystis carinii pneumonia
	Pentam 300	pentamidine isethionate	Anti-Infective Agent Used in the treatment of pneumonia
	Prograf	tacrolimus	Immunosuppressant Used to lower the body's natural immunity in patients who receive organ transplants
		acyclovir sodium	Antiviral Agent Used to treat herpes simplex infections, varicella-zoster (chickenpox) in people with weakened immune systems, and severe genital herpes infections
		dexamethasone sodium phosphate	Anti-Inflammatory Agent; Antiemetic (Gastrointestinal Agent) Used in various applications to treat inflamed areas of the body
		doxorubicin hydrochloride	Antineoplastic Used in the treatment of ovarian cancer and AIDS-related Kaposi's sarcoma
		fluorouracil	Antineoplastic Used to treat cancer, including colon, rectum, breast, stomach, and pancreas
		gentamicin sulfate	Antibacterial Agent Used to treat serious bacterial infections
		vinblastine sulfate	Antineoplastic Used in the treatment of various forms of cancer, including lymphoma and breast cancer





**1. Fujisawa Has Been the Target of Government Investigations**

365. In connection with its scheme to inflate AWP, Fujisawa has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, and the Attorney General for the State of California.

**2. Fujisawa Controls the Published AWP for Its Products**

366. Fujisawa controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, on March 10, 1997, Fujisawa provided MediSpan with an updated listing of pack prices – including AWP – for all of its products. (FJ-MDL 015152-015159).

**3. Fujisawa's AWP Manipulation Benefited Providers at the Expense of the Class**

367. The purpose of Fujisawa's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class. Fujisawa understood that providers and intermediaries sought significant AWP spreads. In a March 1995 Monthly Report, dated March 30, 1995, Fujisawa noted:

We have lost our Vanco business at Chartwell. They have recently been handed an edict to order those products with the largest spread between acquisition cost and AWP. Abbott has unbelievably high Vanco AWP. In an effort to counter this loss I suggested we look at picking up the Cefazolin business where our AWP for one gram Cefazolin is over \$8. Unfortunately our 10 gram price does not follow the same formula and is in the \$45 range while Schein is approximately \$58. We do however have a shot at Cefizox for Medicaid/Medicare patients which make up 50% of Chartwell's patients. Medicaid does not reimburse Chartwell for the Rocephin they currently use and while they will not reimburse for Cefizox either they could acquire Cefizox at a fraction of the cost. They use \$400,000 in Rocephin annually, \$200,000 for Medicaid/Medicare patients. That works out to better than \$100K in savings for Chartwell.

(FJ-MDL 005687-88) (Confidential).



368. Fujisawa, in a conscious effort to increase the spread for providers and intermediaries, changed its AWP's and marketing practices accordingly. In a May 1995 Monthly Report, dated May 30, 1995, Fujisawa addressed its recent decision to increase its AWP for Vancomycin Hydrochloride and aggressively market the resulting spread increase:

Many thanks to Rick and Bruce for adjusting the AWP on the five gram Vanco. This should lead to more business. As I have previously reported, some companies are still using AWP for reimbursement purposes. Chartwell has been told to search for the largest spread and order accordingly. I would have liked to see us match Abbott's AWP for our complete Vanco, and Cefazolin line. I will settle for the five gram at \$1 below Abbott but that means that we still have to compete at the other end of the equation. For example, if Abbott's AWP is \$163 and their contract is \$30 and if our AWP is \$162 we will have to be at least \$29 to have the same spread. Follow?

(FY-MDL 005668-69) (Confidential).

369. In an October 5, 1993 interoffice memorandum discussing Fujisawa's communications with industry pricing compendia, Fujisawa acknowledged that the AWP's for nearly all of its products is inflated at least 33% over direct list prices:

One of the issues regarding our companies AWP listing is that the databases only use our listing as a "Suggested Manufacturers AWP". The standard wholesaler mark-up used by those databases is currently at 25% above direct list price which is our hospital list. Almost all of our products are at 33% or higher above list price.

(FJ-MDL 008346) (Confidential).

370. Further, just as Fujisawa motivates providers to administer drugs based on the AWP, Fujisawa rewards PBMs based on the degree of influence they exert to drive utilization of Fujisawa products. (FJ-MDL 010272-78) (Confidential).

#### **4. Specific Fujisawa AWP's Documented by the DOJ**

371. In a report published by the DHHS (AB-00-86), the DOJ documented at least 35 instances where the published AWP's for various dosages of 6 drugs manufactured by Fujisawa were substantially higher than the actual prices listed by wholesalers. The chart below sets forth



the 6 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Fujisawa in the 2001 *Red Book*.

Drug	The Fujisawa Group's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Acyclovir Sodium	\$565.10 <sup>3</sup>	\$371.50	\$193.60	52%
Dexamethasone Sodium Phosphate	\$1.04 <sup>4</sup>	\$.66	\$.38	58%
Fluorouracil	\$2.87	\$1.20	\$1.67	139%
Gentamicin Sulfate	\$12.64 <sup>5</sup>	\$5.40	\$7.24	134%
Pentamidine Isethionate	\$98.75	\$36.00	\$62.75	174%
Vancomycin Hydrochloride	\$10.97 <sup>6</sup>	\$7.00	\$3.97	57%

(P006299-006316).

#### 5. Inflated AWP's From Fujisawa Price Lists

372. In response to government subpoenas, Fujisawa produced numerous price lists setting forth spreads between AWP's and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Fujisawa has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spreads offered to each specific customer here is not practical.

373. Set forth below in Table 1, however, are the AWP, contract prices and spread of a number of drugs (not already referenced above) included in a Fujisawa customer price list dated August 24, 1995, and their associated AWP spread. (FJ-MDL 013079-81) (Confidential).

<sup>3</sup> Calculation based on the AWP listed in the 1998 *Red Book*.

<sup>4</sup> Calculation based on the AWP listed in the 1998 *Red Book*.

<sup>5</sup> Calculation based on the AWP listed in the 1998 *Red Book*.

<sup>6</sup> Calculation based on the AWP listed in the 1998 *Red Book*.

**Table 1**

<b>Drug</b>	<b>Contract Price</b>	<b>AWP</b>	<b>\$ Diff AWP</b>	<b>% Spread</b>
Triamcinolone	\$14.33	\$17.95	\$3.62	25%
Calcium Gluconate	\$11.50	\$34.00	\$22.50	196%
Cefazolin Sodium	\$139.00	\$367.13	\$228.13	164%
Ceftizoxime Sodium	\$7.50	\$11.86	\$4.36	58%
Amcinonide	\$41.50	\$52.13	\$10.63	26%
Doxycycline Hyclate	\$15.00	\$73.75	\$58.75	392%
Fluphenazine Hydrochloride	\$24.10	\$30.25	\$6.15	25%
Folic Acid	\$7.25	\$11.85	\$4.26	63%
Levothyroxine Sodium	\$3.90	\$38.43	\$34.53	885%
Lidocaine Hydrochloride	\$17.00	\$24.50	\$7.50	44%
Magnesium Sulfate	\$22.00	\$138.25	\$116.25	528%
Mannitol	\$28.00	\$56.50	\$28.50	101%
Neostigmine Methylsulfate	\$8.20	\$89.30	\$81.10	989%
Oxytocin	\$13.50	\$24.50	\$11.00	81%
Potassium Acetate	\$92.00	\$312.40	\$220.40	240%
Potassium Chloride	\$12.25	\$30.50	\$18.25	149%
Potassium Phosphate	\$30.25	\$133.75	\$103.50	342%
Pyridoxine Hydrochloride	\$35.00	\$47.00	\$12.00	34%
Scopolamine Hydrobromide	\$22.00	\$30.00	\$8.00	36%
Selenium	\$18.25	\$195.25	\$177.00	970%

374. Set forth below in Table 2, however, are the AWP, contract prices and spread of a number of drugs (not already referenced above) included in a Fujisawa price list dated November 5, 1996, and their associated AWP spread. (FJ-MDL 008240-53) (Confidential).

**Table 2**

<b>Drug</b>	<b>Wholesaler Price</b>	<b>AWP</b>	<b>\$ Diff AWP</b>	<b>% Spread</b>
Adenocard IV	\$21.95	\$26.34	\$4.39	20%
Adenoscan	\$179.00	\$223.75	\$44.75	25%
Aristocort A	\$7.05	\$8.46	\$1.41	20%
Atropine Sulfate Injection	\$.64	\$1.12	\$.48	75%
Doxorubicin	\$12.44	\$45.50	\$33.06	266%
Furosemide	\$.74	\$.98	\$.24	32%



Drug	Wholesaler Price	AWP	\$ Diff AWP	% Spread
Hydroxyzine Hydrochloride	\$.42	\$.65	\$.23	55%
Protamine Sulfate	\$3.33	\$5.32	\$1.99	60%
Selepen	\$18.24	\$29.93	\$11.68	64%
Sodium Acetate	\$8.81	\$14.63	\$5.82	66%
Sodium Bicarbonate	\$2.04	\$3.33	\$1.29	63%
Sodium Chloride	\$.68	\$1.40	\$.72	106%
Sodium Phosphate	\$5.81	\$9.08	\$3.27	56%
Tracelyte	\$8.26	\$11.57	\$3.31	40%
Vinblastine Sulfate	\$26.50	\$43.23	\$16.73	63%
Water for Injection	\$1.10	\$2.34	\$1.24	113%

375. As set forth above, Fujisawa's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

**L. The GSK Group (GlaxoSmithKline, SmithKline Beecham, Glaxo Wellcome)**

376. The GSK Group has engaged in an organization-wide and deliberate scheme to inflate AWP's. The GSK Group has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below. The specific drugs manufactured and/or distributed by the GSK Group for which relief is sought in this case are set forth in Appendix A and are identified below:

Manufacturer	Brand Name	Generic Name	Therapeutic Category/Usage
GSK GROUP (SmithKline)	Advair Diskus	salmeterol-fluticasone	Bronchodilator (Respiratory Agent) Used for treatment of asthma
Beecham, GlaxoSmithKline and Glaxo Wellcome)	Agenerase	amprenavir	Antiviral Agent Used in treatment of HIV infection
	Alkeran	melphalan	Antineoplastic Used to treat ovarian cancer and a certain type of cancer in the bone marrow
	Amerge	naratriptan succinate	Antimigraine Agent Used for treatment of migraine attacks
	Beconase AQ	beclomethasone dipropionate monohydrate	Anti-Inflammatory Agent Used to treat discomfort of hay fever, other allergies, and other nasal problems





Brand Name (Trade Name)	Generic Name	Therapeutic Category/Usage
Cefin	cefuroxime axetil	Antibacterial Agent Used to treat infections caused by bacteria
Combivir	lamivudine- zidovudine	Antiviral Agent Used in treatment of HIV infection
Daraprim	pyrimethamine	Antiprotozoal Used for treatment of malaria and other protozoal infections
Epivir	lamivudine	Antiviral Agent Used in treatment of HIV infection
Flonase	fluticasone propionate (nasal)	Anti-Inflammatory Agent Used for treatment of allergic and nonallergic rhinitis
Flovent	fluticasone propionate (inh)	Antiasthmatic (Anti-Inflammatory Agent) Used for treatment of asthma
Imitrex	sumatriptan or sumatriptan succinate	Antimigraine Agent Used for treatment of migraine attacks or cluster headaches
Kytril	granisetron hcl	Antiemetic (Gastrointestinal Agent) Used to prevent the nausea and vomiting that may occur after chemotherapy
Lamictal	lamotrigine	Anticonvulsant Used to help control some types of seizures in the treatment of epilepsy
Lanoxin	digoxin	Antiarrhythmic Agent (Cardiovascular Agent) Used to improve the strength and efficiency of the heart, or to control the rate and rhythm of the heartbeat.
Leukeran	chlorambucil	Alkylating Agent (Antineoplastic) Used to treat cancer of the blood and lymph system
Mepron	atovaquone	Antiprotozoal Used to treat and to prevent pneumonia
Myleran	busulfan	Antineoplastic Used to treat some kinds of cancer of the blood.
Navelbine	vinorelbine tartrate	Antineoplastic Used for treatment of lung cancer
Paxil	paroxetine hcl	Antianxiety agent; Antidepressant (Psychotherapeutic Agent) Used in the treatment of various psychotherapeutic disorders
Purinethol	mercaptopurine	Antimetabolite (Antineoplastic) Used to treat some kinds of cancer.





Manufacturer	Trade Name	Generic Name	Indication / Agent Type
	Relenza	zanamivir	Antiviral Agent Used in the treatment of the infection caused by the flu virus (influenza A and influenza B).
	Retrovir	zidovudine	Antiviral Agent Used for treatment of HIV infection
	Serevent	salmeterol xinofoate	Bronchodilator (Respiratory Agent) Used to treat or prevent symptoms of asthma, chronic bronchitis, emphysema, and other lung diseases
	Trizivir	abacavir sulfate-lamivudine-zidovudine	Antiviral Agent Used for treatment of HIV-1 infection
	Valtrex	valacyclovir hcl	Antiviral Agent Used for treatment of shingles and genital herpes
	Ventolin HFA	albuterol sulfate	Bronchodilator (Respiratory Agent) Used for treatment or prevention of bronchospasm
	Wellbutrin	bupropion hcl	Antidepressant (Psychotherapeutic Agent) Used for treatment of depression
	Zantac	ranitidine hydrochloride	Gastrointestinal Agent Used in the treatment of active duodenal ulcer
	Ziagen	abacavir sulfate	Anti Infective Agent Used in the treatment of HIV infection
	Zofran	ondansetron hcl	Antiemetic (Gastrointestinal Agent) Used to treat or prevent the nausea and vomiting that may occur after chemotherapy
	Zofran ODT	ondansetron	Antiemetic (Gastrointestinal Agent) Used to treat or prevent the nausea and vomiting that may occur after chemotherapy
	Zovirax	acyclovir	Antiviral Agent Used for treatment of shingles, genital herpes and herpes simplex
	Zyban	bupropion hcl	Antidepressant (Psychotherapeutic Agent) Used to relieve mental depression. Also used to aid in cessation of smoking
		thioguanine	Antineoplastic Used to treat some kinds of cancer

# 1. The GSK Group Has Been the Target of Government Investigations

377. In connection with its scheme to inflate AWP's, the GSK Group has been investigated by the United States Department of Justice, the Office of Inspector General of the



Department of Health and Human Services, the Attorney General for the State of Texas, the Attorney General for the State of California, and the Attorney General for the State of Nevada, Medicaid Fraud Control Unit.

378. These investigations confirm that the GSK Group has engaged in a deliberate scheme to inflate the published AWP for its drugs.

## **2. The GSK Group's Definition and Understanding of AWP**

379. In a GSK document entitled "Zofran Tablets & Zofran Injection: Sales Training Guide Reimbursement Module" (GSK-MDL-ZN02-035925) (Highly Confidential), GSK defines AWP as follows:

Average Wholesale Price (AWP): The composite wholesale prices charged on a specific commodity that is assigned by the drug manufacturer and is listed in either the Red Book or Blue Book and used by third-party payers as a basis for reimbursement.

(GSK-MDL-ZN02-035985) (Highly Confidential). Thus, by its own definition, GSK recognizes that: (i) AWP should be an average of actual wholesale prices; (ii) the drug manufacturers control the published AWP; and (iii) the published AWP directly affect the payments made by the Class.

## **3. The GSK Group Controls the Published AWP for Its Products**

380. The GSK Group has controlled and set the AWP for its pharmaceutical products during the Class Period. As set forth below, any claim that The GSK Group only reports a WAC to industry compendia and therefore is not responsible for the published AWP is belied by its own documents. For example:

a. In 1991 a Glaxo document entitled "Zofran Third Party Payment Plan," among the many recommendations concerning the pricing of its then new drug Zofran was the recommendation that "In establishing direct-to-wholesaler and *Red Book* wholesale prices for Zofran, Glaxo should take into consideration physicians' expected profit margins." (GSK-MDL-ZN02-03428) (Highly Confidential).



b. Expanding further on the recommendation above, elsewhere in the same document it is stated: "Because insurers often reimburse physician-infused drugs up to the average wholesale price (AWP), the doctor's profits are determined by the differential between the AWP and the price they pay to the wholesaler or pharmacy supplier. The company should ensure that doctors will make acceptable return on Zofran® by managing markups through the distribution chain." (GSK-MDL-ZN02-034366) (Highly Confidential).

381. As do all of the Defendants, GSK has direct control over the "markups" in the distribution chain for its products. That control results from an ability to set the published AWP.

**4. The GSK Group's AWP Manipulation Benefited Providers at the Expense of Plaintiffs and the Class**

382. GSK acknowledged that the AWP, as published in industry compendia, was used as the basis for most payments by third party payors. GSK's own documents state, "Most, but not all, plans determine a payment for new drugs, based on the drug's cost as listed in the *Red Book* and pay all providers that amount less any patient co-payments." (GSK-MDL-ZN02-035965) (Highly Confidential). Elsewhere in the same document GSK acknowledges: "Payment amounts for most payers is usually based on the AWP as listed in *Red Book*, however, co-payments, especially for Zofran Tablets will be required." (GSK-MDL-ZN02-035973) (Highly Confidential).

383. The purpose of The GSK Group's AWP manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class. That scheme has resulted in a system where drugs are administered based upon a profit incentive to physicians and other intermediaries and which results in an incentive to prescribe more expensive, rather than cheaper drugs. In talking points prepared in advance of negotiations with clinics, Glaxo instructed its sales people to remind customers that "Cheaper is not necessarily a prudent medical or business decision" and that "Cheaper ? Good medicine or Good Business!" (GSK-MDL-ZN02-077818-19) (Highly Confidential).



384. The GSK Group tried to maximize spread because it understood that its customers routinely engaged in “spread shopping” – comparing its AWP’s with those of its competitors in order to determine the greatest spread (and therefore sell or administer the drug with the greatest spread).

385. Perhaps the most flagrant example of the GSK Group’s fraudulent manipulation of AWP’s is found in the documents relating to Glaxo’s Zofran® and SKB’s Kytril®. These two drugs both minimize the nausea associated with chemotherapy, and, prior to the merger of Glaxo and SKB, competed head-to-head in the same market. As detailed below, much of that competition concerned which product could generate *the greater spread*, or profit, for physicians; not over which product was better for patients.

**5. Glaxo’s Zofran®**

386. A Glaxo marketing document, sent to its sales and marketing personnel via U.S. Mail and interstate wire facilities, advises that they should emphasize to medical providers both the benefits of Zofran® and the financial benefits of the spread. Specifically:

By using a 32 mg bag, the physician provides the most effective dose to the patient and increases his or her profit by \$ \_\_\_\_\_ in reimbursement as well as paying no upcharges for the bag or admixing

387. A follow-up internal Glaxo memo, dated October 27, 1994, entitled “Zofran Pricing Recommendation,” states: “Physician reimbursement for the administration of intravenous oncology drugs is based on the spread between acquisition cost and the AWP.” The memo later notes that “Kytril carries a 20% spread between List Price and AWP compared to Zofran which carries a 16 2/3% spread providing SKB with a significant advantage in the clinic setting with respect to reimbursement.” (P007015-P007490, at P007487-P007490).

388. In response to the larger spread being offered on Kytril, this same internal document discusses several options to increase Zofran’s spread “to balance the reimbursement



spread which currently exists between Zofran and the market in which it competes. . . .” The pricing options considered for increasing the “spread” for Zofran® included:

Recommendation #1

4.5% price increase	\$178.97 to \$187.02
Increase AWP	16 2/3% to 20% \$214.76 to \$233.78 (8.5%)
3% Wholesaler Rebate (11/14/94 - 1/31/95)	\$187.02 to \$172.92 (chargeback) \$179.92 to \$167.31 (rebate)

389. In an effort to hide the fact that Glaxo was increasing the spread for Zofran®, Glaxo elected to not only increase its AWP and provide rebates, but to also include a small actual price increase. In describing the reason for an increase in the actual selling price, an internal Glaxo document states:

The recommended multi-tiered modification to current promotion, should also provide an immediate resultant impact to weekly unit sales without being easily intelligible by SKB as to the means by which this was achieved. Thus, providing additional time before a competitive response would be delivered.

390. Glaxo internal documents, however, recognized that as a result of its increasing the spread for Zofran®, SKB would have two options:

- Option 1: Decrease the purchase price of Kytril.
- Option 2: Take a price increase to raise the AWP while maintaining purchase price to generate a higher spread than \$52.00.

(P007015-P007490, at P007489-P007490).

391. In order to increase the spread for Zofran®, Glaxo increased the AWP for a 20 ml injection of Zofran® to \$233.02 in January of 1995. This was discussed in an October 27, 1994 memo entitled “Zofran Pricing Recommendation” and further discussed at a Glaxo pricing committee meeting on November 4, 1994. (P007015-P007490, at P007487-P007490).



392. In February 1995, the *Florida Infusion Chemo Net* reported that Glaxo was increasing the published AWP for Zofran®, but was specifically offering incentives to lower the actual price offered to medical providers, thereby allowing medical providers to seek reimbursement at inflated prices. Specifically:

Effective January 3, 1995. Glaxo has increased the acquisition costs of Zofran injection. The new AWP is set at \$233.02. However, the company has provided incentives to the market place which will ensure that Zofran price to physicians and clinics will be lower than the contractual price available prior to the increase.

Letter from Bliley, Chairman Commerce Committee to Nancy Min DeParle, Sept. 25, 2000 (P007015-P007490, at P007046).

393. Glaxo was fully aware that the larger spread for its product would be a big selling point. A flier in GSK's possession but produced by wholesaler NSS advertises to physicians that:

Your Zofran™ Deal Just Got Better!!!

(Effective 4:00pm January 9, 1995)

\*New AWP \$233.02

New Price from NSS

\*\* \$161.00 \*\*

(GSK-MDL-ZN02-034942) (Highly Confidential).

394. In March 1996, Glaxo again increased the AWP for Zofran® by 4.8%. In response, SKB immediately increased the AWP for Kytril by 4.8%. An internal SKB memo, dated March 21, 1996, entitled "Kytril Price Increase," states:

I recommend a 4.8% price increase effective March 25, 1996 for all Kytril presentations. This is in response to a Glaxo Wellcome price increase of 4.8% for Zofran effective March 8, 1996.

(P007015-P007490, at P007078).





395. In a Glaxo internal memo dated October 25, 1994, entitled "Issue considerations on Zofran pricing strategies," Nancy Pekarek (a communications manager for Glaxo who later became Vice-President of U.S. Corporate Media Relations) recognized the implications of increasing the AWP to create a better spread:

If Glaxo chooses to increase the NWP and AWP for Zofran in order to increase the amount of Medicaid reimbursement for clinical oncology practices, we must prepare for the potential of a negative reaction from a number of quarters. Some likely responses:

(1) Press: Glaxo's health care reform messages stressed the importance of allowing the marketplace to moderate prices. On the surface, it seems that in response to the entrance of a competitor in the market, Glaxo has actually raised its price on Zofran-perhaps twice in one year. How do we explain that price increase on a drug that is already been cited in the press as one of, if not the most expensive drug on the hospital formulary?

*If we choose to explain the price increase by explaining the pricing strategy, which we have not done before, then we risk further charges that we are cost shifting to government in an attempt to retain market share.*

(2) Congress: Congress has paid a good deal of attention to pharmaceutical industry pricing practices and is likely to continue doing so in the next session. How do we explain to Congress an 8% increase in the NWP between January and November of 1994, if this policy is implemented this year? How do we explain a single 9% increase in the AWP? *What arguments can we make to explain to congressional watchdogs that we are cost-shifting at the expense of the government?* How will this new pricing structure compare with costs in other countries?

(3) *Private insurers, out-of-pocket payers: These groups, and perhaps others, are likely to incur greater costs as a result of this pricing strategy. How will they be affected? What response do we have for them?*

(GSK-MDL-Z01-05675) (Highly Confidential) (emphasis added).

396. Glaxo also knew that Zofran® products were being marketed based on the spread between the actual cost and the published AWP. For example, when Glaxo introduced the Zofran® premixed IV bag, it used marketing materials which stated:



Convenient  
Costs Less Than Vial  
Higher AWP  
Better Reimbursement

(P007015-007490, at P007243).

397. Other internal Glaxo documents directly compared the “Profit Per Dose” and “Profit as %” and “Profit Per Vial” of Zofran® to Kytril®. These comparisons also identified that in order to increase the spread for Zofran®, Glaxo included “early pay disc” and “rebates” and “incentive.”

398. In marketing the new Zofran® premixed IV bag, Glaxo produced and used a document entitled “Profit Maximization – It’s In the Bag.” This document compared Kytril® to Zofran® based upon its total return of investment (ROI). Specifically, Glaxo’s marketing materials including the following chart:

	Cost	AWP	Potential Reimbursement/ Patient	Reimbursement/ Year	ROI
Zofran 32mg bag	\$110.41	\$195.00	84.59	\$13,957,350	76.6%
Kytril 1 mg vial	\$102.73	\$175.00	72.27	\$11,924,000	70.3%

(P007114) (Highly Confidential).

399. Another Glaxo document entitled “Profit Maximization – Continued” reflects how much “Total Revenue Potential” there was for using Zofran® because of the large spread between the cost and reimbursement for various Zofran® products. (P007115) (Highly Confidential).

400. An internal SKB document further acknowledges Glaxo’s attempts to use and market the spread and its effects on the Class:

*As of late, Glaxo promotional efforts have focused almost entirely on the financial benefits of “up-dosing” rather than efficacy of Zofran. Though physicians have certainly benefited financially from such tactics, it is costing 3<sup>rd</sup> party payers and patients more for medication.*



(P007115-P007490, at P007138-P007139) (Highly Confidential) (emphasis added).

401. In a September 27, 2000 article in *USA Today*, Glaxo spokesman Rick Sluder (who received a copy of the October 24, 1994 memo described herein) discussed the issue of the spread and blamed a system that set up a reimbursement method that relies on average wholesale prices which are not actually “representative of actual prices.” Mr. Sluder, admitting that Glaxo changed its wholesale prices to keep up with competitors who changed wholesale prices, stated “We didn't want to put ourselves at a price disadvantage.” Mr. Sluder also admitted that the marketing of Glaxo drugs is based, in part, on the spread. In fact, he noted that Glaxo’s sales staff is briefed on the price advantages to doctors who bill and get reimbursed based upon the AWP. (E-mail from Clapton to Vaughan dated Sept. 27, 2000 citing “How Drug Makers Influence Medicare Reimbursements to Doctors; WALL STREET JOURNAL (P007501-P007506).

#### 6. SKB’s Kytril

402. According to its internal documents (and prior to selling Kytril®’s global rights to the Roche Group in December 2000), SKB also knew that by creating the spread for Kytril®, it could directly affect the amount of revenue medical providers receive and thereby affect overall demand for Kytril®. Specifically, an August 6, 1996 internal SKB memo stated:

In the clinic setting however, since Medicare reimbursement is based on AWP, product selection is largely based upon the spread between acquisition cost and AWP.

\* \* \*

From this analysis, there seems to be no other reason, other than profitability, to explain uptake differentials between the hospital and clinic settings, therefore explaining why physicians are willing to use more expensive drug regimens.

(P007015-P007490, at P007249-P007250).

403. Internal SKB documents reveal how it marketed the spread. One internal document entitled “Price Comparison of Kytril and Zofran for Reimbursement” discussed how



much additional revenue and “spread per patient” a medical provider would make by using Kytril® due to its larger spread. It stated:

Kytril reimbursement for 5 patients treated \$540.00 - Kytril 6 treated patients \$423.12

Difference = \$117.00 every 6 patients.

Use 5ht3 5 times a day = \$2,340.00 month. \$28,080.00 year more!

(P007015-P007490, at P007117).

404. Other internal SKB documents entitled “Cost v. Profit” and “Kytril Profit Model” compare Kytril® and Zofran® to demonstrate how much additional profit/revenue the medical provider will receive by using Kytril®.

**7. General Counsel Correspondence Between Glaxo and SKB**

405. Most revealing is an exchange of correspondence between counsel for Glaxo and SKB over Zofran® and Kytril® in which each accuse the other of fraud.

406. On February 6, 1995, Timothy D. Proctor, Senior Vice President, General Counsel and Secretary for Glaxo, sent a letter to J. Charles Wakerly, Senior Vice President, Director and General Counsel of SKB informing him of “several issues pertaining to the advertising and marketing of Kytril”:

Glaxo’s sales representatives have encountered a substantial amount of what appear to be “homemade” Kytril vs. Zofran cost comparisons. It is our understanding that many of these pieces have been generated through a company-provided lap top computer program.

. . . .

In addition, a significant number of these pieces (see Exhibits F-J) contain direct statements or make references as to how institutions can increase their “profits” from Medicare through the use of Kytril. Some even go so far as to recommend that the medical professional use one vial of Kytril for two patients (see Exhibit F) but charge Medicaid for three vials. This raises significant fraud and abuse issues which I am sure you will want to investigate.”

(P007015-P007490, at P007123-P007126).



407. On February 22, 1995, Ursualy B. Bartels, Vice President and Associate General Counsel for SKB, wrote in response that SKB was investigating Glaxo's claims and asked whether Glaxo had specific information regarding the improper marketing of Kytril. Mr. Bartels also accused Glaxo of using false and misleading marketing materials regarding Zofran that rely on the medical providers' ability to garner more profit. Specifically, he stated:

Regarding similar concerns, we would like to draw your attention to reports we are receiving from our field force regarding reimbursement issues. In an apparent effort to increase reimbursement to physicians and clinics, effective 1/10/95, Glaxo increased AWP for Zofran by 8.5%, while simultaneously fully discounting this increase to physicians. The latter was accomplished by a 14% rebate available to wholesalers on all non-hospital Zofran sales on the multi-dose vial. ***The net effect of these adjustments is to increase the amount of reimbursement available to physicians from Medicare and other third party payors whose reimbursement is based on AWP.*** Since the net price paid to Glaxo for the non-hospital sales of the Zofran multi-dose vial is actually lower, it does not appear that the increase in AWP was designed to increase revenue per unit to Glaxo. ***Absent any other tenable explanation, this adjustment appears to reflect an intent to induce physicians to purchase Zofran based on the opportunity to receive increased reimbursement from Medicare and other third party payors. In fact, we have had numerous verbal reports from the field concerning Glaxo representatives who are now selling Zofran based on the opportunity for physicians to receive a higher reimbursement from Medicare and other third-party payors while the cost to the physician of Zofran has not changed.***

(P007015-007490, at P007478-P007481) (emphasis added).

408. On April 25, 1995, Adrianna L. Carter, Glaxo Assistant General Counsel, responded to SKB's February 22, 1995 letter. Ms. Carter provided, pursuant to SKB's request, numerous additional examples of false and misleading marketing materials concerning "cost comparisons distributed to health care professionals by SmithKline representatives." Ms. Carter also denied SKB's allegations regarding "fraud and abuse" over the price increase of Zofran. However, Ms. Carter did admit that the AWP price increase for Zofran® does not affect the



actual cost to medical providers and that Glaxo's sales representatives were using the "spread" to gain market share. Specifically, Ms. Carter stated:

It is true that, despite a price increase, some physicians and other healthcare professionals will not see the higher price as the result of rebates or other incentives.

\* \* \*

It is also true that our sales representatives have been explaining the relationship between the price and Medicare reimbursement for Zofran to physicians.

\* \* \*

Finally, Ms. Carter stated that despite SKB's assertions that any alleged improper marketing of Kytril would end, "Unfortunately, despite your efforts, these activities are still ongoing."

(P007015-007490, at P007127-P007131).

409. The fact that Glaxo and SKB each accused the other of similar conduct, but neither took any action to bring it to the attention of the public or the appropriate authorities, is evidence that each of them were engaged in an ongoing scheme to defraud the Plaintiffs and Class.

#### **8. Other Improper Incentives**

410. In addition to marketing the spread on its products, the GSK Group has also used other methods to induce physicians and other intermediaries to use its drugs such as rebates and free samples in order to increase the spread between acquisition costs and reimbursement.

411. In an e-mail by GSK account representative Paul J. Ostruszka explaining how he was able to increase the market share of Zofran over Anzimet, among the suggested techniques he recommends to his fellow GSK account reps is "Ask your customers how much JUST 1 FREE Zofran Tablet Sample is WORTH" (emphasis in original). This e-mail was later forwarded to the entire Zofran team. (GSK-MDL-ZN02-077634).





412. An advertisement in the *Florida Infusion Chemo net* reveals that SKB created the spread not only by artificially inflating the AWP for Kytril®, but also by providing discounts and rebates. Specifically, the advertisement states:

We have been notified that, effective April 1, 1995, SmithKline's long running promotional rebate for Kytril purchases will come to a very successful conclusion.

(P007015-007490, at P007187).

413. SKB also knew that medical providers were billing Plaintiffs and the Class for a 1 mg single dose vial per patient, but actually were using less than the full single dose per patient. Depending on the weight of a patient, medical providers were able to use less of the drug, *i.e.*, the lighter the patient, the less Kytril® was needed. SKB subsequently introduced a Kytril® 4 mg Multi-Dose vial that allowed medical providers to bill 6 treatments for the cost of 4. For example, an SKB marketing document entitled "Kytril Vial Usage" states, "You can use only three vials of Kytril for four patients." (P007015-007490, at P007068 and P007455).

414. SKB also used other financial incentives to decrease medical providers' costs and thereby increase profits. For example, SKB promised to contribute to research and education programs through the OnCare Foundation if OnCare agreed to use Kytril instead of a competing drug. (P007015-007490, at P007061).

#### **9. Specific GSK Group AWP's Documented by the DOJ**

415. In a report published by the DHHS (the "DHHS Report"), the DOJ documented that the published AWP's for various dosages of Zofran and Kytril manufactured by The GSK Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the AWP's identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by The GSK Group in the 2001 *Red Book*.



Drug	GSK 2001 Red Book AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Ondanestron (Zofran)	\$128.24	\$22.61	\$101.63	450%
Granisetron (Kytril)	\$195.20	\$139.04	56.16	40%

(P006299-P006316).

416. As set forth above, the GSK Group's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

#### M. Hoffman-LaRoche

417. Hoffman-LaRoche engages in an organization-wide and deliberate scheme to inflate AWP's. Hoffman-LaRoche has stated fraudulent AWP's for all or almost all of its drugs, including, Kytril and Cellcept. The specific drugs of Hoffman-LaRoche for which relief is sought in this case are set forth in Appendix A and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category
HOFFMAN-LaRoCHE	Cellcept	mycophenolate mofetil	Immunosuppressant Used to lower the body's natural immunity in patients who receive organ transplants
	Cellcept IV	mycophenolate mofetil hcl	Immunosuppressant Used to lower the body's natural immunity in patients who receive organ transplants
	Kytril	granisetron hcl	Antiemetic (Gastrointestinal Agent) Used to prevent the nausea and vomiting that may occur after treatment with anticancer medicines (chemotherapy) or with radiation therapy

#### 1. Hoffman-LaRoche Controls the Published AWP for Its Products

418. Hoffman-LaRoche has controlled and set the AWP's for its pharmaceutical products through direct communications with industry compendia during the Class Period.



## 2. Inflated Hoffman-LaRoche AWP's From Hoffman LaRoche Price Lists

419. According to the information provided on Hoffman-LaRoche's own website, the published AWP's for Kytril and CellCept were higher than the actual prices provided to wholesalers.

## 3. Hoffman-LaRoche Provided Free Goods and Other Incentives

420. In addition to marketing the spread, Hoffman-LaRoche has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, Hoffman-LaRoche provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

421. As set forth above, Hoffman-LaRoche's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

## N. Immunex

422. Immunex engages in an organization-wide and deliberate scheme to inflate AWP's. Immunex has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below. The specific drugs of Immunex for which relief is sought in this case are set forth in Appendix A and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Use
IMMUNEX	Leukine	sargamostin	Antineutropenic Agent Used to help produce bone marrow and white blood cells
	Novantrone	mitoxane hydrochloride	Antineoplastic Used in the treatment of multiple sclerosis and various forms of cancer



Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Uses
	Thioplex	lyophilized thiotepa	Antineoplastic Used in the treatment of ovarian and breast cancer, lymphoma and bladder tumors
		leucovorin calcium	Antianemic Agent (Blood Modifier) Used in the treatment of anemia
		methotrexate sodium	Antineoplastic Used in the treatment of various forms of cancer

### 1. Immunex Has Been the Target of Government Investigations

423. In connection with its scheme to inflate AWP, Immunex has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, and the Attorney General for the State of California.

### 2. Immunex Definition and Understanding of AWP

424. Immunex's internal documents reveal that it understood how industry compendia defined and utilized AWP:

#### Red Book Definition of AWP

The average wholesale price as we consider it here at Red Book is the price a retail hospital or pharmacy pays if purchases product from wholesaler before the discount if any.

#### Blue Book Definition of AWP

AWP represents an average price which a wholesaler would charge a pharmacy for a particular product.

(IAWP002238) (Highly Confidential).

### 3. Immunex Controls the Published AWP for its Products

425. Immunex controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia during the Class Period. In 2000, in the midst of numerous government investigations concerning AWP manipulation, Immunex denied



responsibility for controlling the published AWP for its products. For example, in an October 26, 2000 letter to *Red Book*, Immunex states in pertinent part:

As requested, enclosed please find an updated summary of list pricing and package information for Immunex products. Please note that Immunex Corporation is not responsible for setting the Average Wholesale Price (AWP). Therefore, we do not set or approve AWP information for any Immunex products.

(IAWP023473) (Highly Confidential). Previously, in a 1996 interview, an Immunex spokesperson had informed Barron's that "drug manufacturers have no control over the AWP's published." (IAWP003071) (Hooked on Drugs," Barron's, Jun. 10, 1996).

426. Immunex's internal documents, however, establish that it controlled the AWP for all of its products throughout the Class Period. For example:

a. A January 12, 1996 letter from *Red Book* to Immunex, in pertinent part, states:

This letter is a confirmation letter that we have received and entered your latest AWP price changes in our system.

(IAWP008102) (Highly Confidential).

b. A January 12, 1995 letter from Immunex to *Red Book* states:

Below you will find a list of new suggested Average Wholesale Prices (AWPs) for selected Immunex products, along with a new NDC ... all effective January 10, 1995 ... Please update your databases accordingly. A new copy of Immunex's Average Wholesale Price Product Pricing Guide will be sent to you next week.

(IAWP016500) (Highly Confidential).

**4. Immunex's AWP Manipulation Benefited Providers at the Expense of the Class**

427. The purpose of Immunex's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the



Class. Immunex understood that providers and intermediaries were reimbursed at AWP – and benefited from a larger spread.

a. In an internal document entitled “Health Care Policy Fast Facts,” created in 1995, Immunex urged its sales personnel to remember “[p]hysician’s offices use their own charge schedule for billing purposes, and get reimbursed at AWP, based on the published prices in the pricing databases.” (IAWP012961) (Highly Confidential).

b. Recently, in a January 3, 2000 interoffice memo, Immunex discussed the significant revenues to be made by providers which used its Leucovorin and Methotrexate products. Specifically, Immunex stated that, “Leucovorin and Methotrexate represent significant revenue sources for the physician office or clinic. Due to the ‘spread’ (difference between acquisition cost and AWP), physicians have reaped substantial profits.” (IAWP051149-52) (Highly Confidential).

428. Immunex, in a conscious effort to increase the spread for providers and intermediaries, changed its AWP’s and marketing practices accordingly. In a February 21, 1997 internal memo discussing reimbursement on its products, in pertinent part, Immunex stated:

The following are the reimbursement schema for Leukine, Novantrone, Thioplex and Leucovorin:

Here’s the way it works [for Leukine] – the Red Book Price (AWP) for our 250 mcg is \$117.79 and \$221.71. **However**, payors take the \$117.79 and divide it by 5, now that we bill per 50 mcg increments. This is equal to \$23.56 per 50 mcg, hence reimbursement on a 500 mcg vial is \$235.60. We need to take into account that in some AOR markets they get AWP or AWP plus a percentage, in others, depending on the makeup of the patient population, they may only get the 80% Medicare allowable (\$188.48). So here’s what the spread looks like:

\$235.60 (AWP)	\$188.48 (80% Medicare allowable)
- \$112.06 (AOR contract price)	- \$112.06
+ \$123.54 per 500 mcg vial (110% spread)	\$76.42 (68% spread)

(IAWP008528) (Highly Confidential) (emphasis in original).





429. Immunex performed an analysis of competitive AWP pricing (IAWP003407-13) (Highly Confidential) and established a “Reimbursement Hotline” for a number of its products (IAWP016686-88) (Highly Confidential).

430. Immunex, through its employees and agents, also provided free samples of its drugs to customers. (IAWP005418) (Highly Confidential) The free samples would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class.

##### **5. Specific Immunex AWP Documented by the DOJ**

431. In a report published by the DHHS (the “DHHS Report”), the DOJ documented at least 7 instances where the published AWP for various dosages of 2 drugs manufactured by Immunex were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 2 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ’s determination of an accurate AWP for that particular dosage, based upon wholesalers’ price lists, with the AWP reported by Immunex in the 2001 *Red Book*.

<b>Drug</b>	<b>2001 <i>Red Book</i> AWP</b>	<b>DOJ Determined Actual AWP</b>	<b>Difference</b>	<b>Percentage Spread</b>
Leucovorin Calcium	\$137.94	\$14.58	\$123.36	846%
Methotrexate Sodium	\$20.48	\$7.10	\$13.38	188%

(P006299-P006316).

432. In a report published by DHHS in 1997, the Department undertook an analysis of the twenty drug codes that represented the largest dollar outlays to the Medicare Program and compared Medicare’s payments with the prices available to the physician and supplier communities. For mitoxantrone hydrochloride, sold by Immunex under the brand name Novantrone, the DHHS found that Medicare paid \$172.81, while the actual average wholesale



price was \$142.40, resulting in a spread of 21.36%. “Excessive Medicare Payments for Prescription Drugs” (Dec. 1997).

**6. Inflated AWP From Immunex Price Lists**

433. In response to government subpoenas, Immunex produced numerous price lists setting forth spreads between AWP and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Immunex has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers.

434. As set forth above, Immunex’s scheme to inflate its reported AWP and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

**7. Immunex Concealed Its AWP Manipulation**

435. Immunex deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, under the guise of “simplifying” its product listings, on June 3, 1994, Immunex instructed the *Red Book* to “delete all references to Direct Price for all Immunex products, effective immediately” and confirmed that “only AWP (Average Wholesale Price) w[ould] be listed for [its] products[.]” (IAWP016524) (Highly Confidential). Immunex effectively hid the AWP spread from Plaintiffs and the Class.

**O. The Johnson & Johnson Group (J&J, Centocor and Ortho)**

436. The Johnson & Johnson Group engages in an organization-wide and deliberate scheme to inflate AWP. The Johnson & Johnson Group has stated fraudulent AWP for all or almost all of its drugs, including those set forth below. The specific drugs of the Johnson & Johnson Group for which relief is sought in this case are set forth in Appendix A, and are set forth below:



Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Uses
JOHNSON & JOHNSON GROUP (J&J, Janssen, McNeil, Ortho and Centocor)	Aciphex	rabepazole sodium	Gastric Acid Pump Inhibitor (Gastrointestinal Agent) Used in the treatment of gastroesophageal reflux disease and duodenal ulcers
	Bicitra	sodium citrate & citric acid	Alkalizer Used in the prevention of kidney stones
	Duragesic	fentanyl	Analgesic Used in the treatment of chronic pain
	Elmiron	pentosan polysulfate sodium	Anti-Inflammatory Agent Used for relief of pain associated with interstitial cystitis
	Erycette	erythromycin	Antiacne Agent; Antibacterial Agent Used to help control acne
	Flexeril	cyclobenzaprine	Skeletal Muscle Relaxant (Analgesic) Used in the treatment of muscle spasm associated with musculoskeletal conditions
	Floxin	ofloxacin	Antibacterial Agent Used in the treatment of pneumonia, bronchitis, gonorrhea and certain other infections
	Grifulvin	griseofulvin microsize	Antifungal Agent Used to treat fungus infections of the skin, hair, fingernails, and toenails
	Haldol	haloperidol lactate	Antiemetic (Gastrointestinal Agent); Antipsychotic (Psychotherapeutic Agent) Used to treat nervous, mental, and emotional conditions
	Haldol Decanoate	haloperidol decanoate	Antiemetic (Gastrointestinal Agent); Antipsychotic (Psychotherapeutic Agent) Used to treat nervous, mental, and emotional conditions
	Levaquin	levofloxacin	Antibacterial Agent Used to treat bacterial infections in many different parts of the body
	Monistat	miconazole nitrate	Antifungal Agent Used in the treatment of yeast infections
	Mycelex	clotrimazole	Antifungal Agent Used in the treatment of candidiasis and tinea versicolor
	Pancrease	amylase-lipase-protease	Digestant; Enzyme, Pancreatic (Gastrointestinal Agent) Used in the treatment of gastrointestinal disorders



Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Use
	Parafon Fort	chlorzoxazone	Skeletal Muscle Relaxant (Analgesic) Used to relax certain muscles and relieve the pain and discomfort caused by strains, sprains, or other injuries to muscles
	Polycitra	potassium & sodium citrates w/ citric acid	Alkalizer Used in the prevention of kidney stones
	Procrit	epoetin alfa	Antianemic Used in the treatment of anemia in HIV-infected, cancer or chronic renal failure patients
	Regranex	becaplermin	Biological Response Modifier Used in the treatment of diabetic neuropathic ulcers
	Remicade	infliximab	Anti-Inflammatory Agent; Antirheumatic Agent Used to treat Crohn's disease and rheumatoid arthritis
	Reminyl	galantamine hydrobromide	Cholinesterase Inhibitor (Central Nervous System Agent) Used in the treatment of dementia of the Alzheimer's type
	Renova	tretinoin	Antiacne Agent Used for mitigation of fine wrinkles and other attributes of facial skin
	Retin-A	tretinoin	Antiacne Agent Used to treat acne
	Retin-A Micro	tretinoin microsphere	Antiacne Agent Used to treat acne
	Risperdal	risperidone	Antipsychotic Agent (Psychotherapeutic Agent) Used to treat the symptoms of psychotic disorders
	Spectazole	econazole nitrate	Antifungal Agent Used to treat infections caused by a fungus
	Sporanox	itraconazole	Antifungal Agent Used in the treatment of various fungal infections
	Terazol	terconazole vaginal	Antifungal Agent Used to treat yeast (fungus) infections of the vagina
	Testoderm	testosterone	Androgen; Antianemic Agent; Antineoplastic Used for replacement therapy in males with a deficiency or absence of testosterone



Manufacturer	Brand Name (if applicable)	Generic Name	Indication and/or Use
	Tolectin	tolmetin sodium	Antirheumatic Agent Used to relieve some symptoms caused by arthritis
	Topamax	topiramate	Anticonvulsant Used to help control some types of seizures in the treatment of epilepsy
	Tylox	acetaminophen w/ codeine	Analgesic Used to relieve pain.
	Tylenol with codeine		
	Ultracet	tramadol- acetaminophen	Analgesic Used to relieve pain
	Ultram	tramadol hcl	Analgesic Used for management of pain
	Urispas	flavoxate hydrochloride	Autonomic Nervous System Agent Used in the treatment of symptoms of various urologic disorders.
	Vascor	bepiridil hcl	Antianginal Agent Used to relieve and control angina pectoris and hypertension

**1. The Johnson & Johnson Group Has Been the Target of Government Investigations**

437. In connection with its scheme to inflate AWP's, the Johnson & Johnson Group has been investigated by the General Accounting Office and the Office of the Attorney general for the Commonwealth of Massachusetts.

438. J&J's internal documents reveal that it was familiar with and understood how industry compendia defined and utilized AWP's. For example, in a rebate agreement between J&J and Merck-Medco Managed Care, Inc. dated December 19, 1996, the parties defined AWP as meaning "the average wholesale price as published in the most current version of either First Data Bank or the Red Book." (J&J000599) (Highly Confidential).

439. The Johnson & Johnson Group has engaged in an ongoing deliberate scheme to inflate AWP's and to market the spread to increase the sales of its products. In a report published by the GAO, federal investigations have documented fraudulently inflated AWP's reported for



epoetin alfa (sold by J&J as Procrit). J&J is identified in various annual *Red Book* publications as one of two sources for epoetin alfa. The other source for epoetin alfa is Defendant Amgen.<sup>7</sup>

440. In September 2001, the GAO reported that epoetin alfa accounted for the second highest percentage of Medicare expenditures on drugs in 1999, accounting for 9.5% of spending for prescription drugs by Medicare in 1999 and for 3.4% of all Medicare allowed services. These massive federal expenditures for epoetin alfa, caused by the J&J Group and Amgen's AWP scheme as well as the inflated cost to Plaintiffs and members of the Class, are even more outrageous given the fact that the research and development of epoetin alfa was originally underwritten by grants from the federal government.<sup>8</sup>

441. By way of further example, the J&J Group has deliberately overstated and continues to overstate the AWP for Remicade®. The published AWP for Remicade® continued to increase each year during the class period. For example, the AWP was listed as \$611.33 for a 100 mg vial of Remicade® as of November 1999, and rose to \$665.65 when listed in the 2001 edition of the *Red Book*. At the same time, J&J deliberately marketed and promoted the sale of Remicade® to physicians based on the availability of inflated payments made by Medicare, assuring them that they would make a significant profit from the purchase of Remicade® as a result of the spread between the actual price to physicians and reimbursement based on the published AWP.

442. The J&J Group created promotional materials and worksheets to allow them to market the spread between the published AWP and the actual selling price to doctors. For example, a publication accessible through Defendants' web sites entitled "Office-Based Infusion Guide" demonstrates Defendants' aggressive marketing of this spread, specifically noting that,

<sup>7</sup> Amgen markets epoetin alfa for use in the treatment of dialysis patients while the right to market epoetin alfa for all other uses is licensed to Defendant J&J.

<sup>8</sup> Epogen® and Procrit® are based on different uses of a patented process technology developed at Columbia University with support from grants from the NIH. Columbia licensed their technology to Amgen for Epogen® and to Johnson & Johnson for Procrit®. *NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected*, Department Of Health And Human Services National Institutes Of Health, July 2001.





“[d]epending on reimbursement, office-based infusion may provide a financial impact to a physician’s practice.” Moreover, the “Financial Analysis” section of the guide includes a “REMICADE® (infliximab) Financial Impact Worksheet,” which enables doctors see in actual dollars how much additional revenue the use of Remicade® would bring to their practice.

443. As set forth above, the J&J Group’s scheme to inflate its reported AWP’s and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

444. Set forth below in Table 1 are the contract prices (not already referenced above) included in a J&J contract price list (effective from April 1, 1997 through March 31, 1998) contained in a supply agreement with Managed Healthcare Associates, Inc. dated March 17, 1997 and the AWP published in the 1997 *Red Book*, and their associated AWP spread. (J&J000121-23) (Highly Confidential).

**Table 1**

Drug	Contract Price	AWP	\$ Diff AWP	% Spread
Procrit (epoetin alfa)	\$950.00 (4000 u/ml 25x1 ml vials)	\$1200	\$250	20.8%
Ultram (tramadol hcl)	\$53.97 (1x100 50 mg)	\$62.34	\$8.37	13.4%
Duragesic fentanyl transdermal)	\$44.94 (25M 25mcg/hr 1x5)	\$53.94	\$9	16.7%
Floxin (ofloxacin)	\$276.89 (1x100 btls 200 mg/case)	\$332.28	\$55.39	16.7%
Propulsid (cisapride)	\$56.62 (10mgx100)	\$67.96	\$11.34	16.7%
Risperdal (risperidone)	\$335.59 (3 mg 1x100)	\$402.72	\$67.13	16.7%
Topamax tiramate)	\$123.00 (100 mg 1x60)	\$147.60	\$24.6	16.7%

## 2. J&J Concealed Its AWP Manipulation

445. J&J deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. J&J routinely required that its customers keep secret the prices they were being charged for J&J drugs. (J&J001022; J&J000110; J&J001430; J&J001483).



**P. Novartis**

446. Novartis engages in an organization-wide and deliberate scheme to inflate AWP's. Novartis has stated fraudulent AWP's for many of its drugs. The specific drugs of Novartis for which relief is sought in this case are set forth in Appendix A.

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
NOVARTIS	Clozaril	clozapine	Antipsychotic (Psychotherapeutic Agent) Used to treat schizophrenia
	Combipatch	estradiol & norethindrone acetate	Hormone Used to treat symptoms of menopause
	Comtan	entacapone	Antidyskinetic Agent Used in combination with levodopa/carbidopa to treat Parkinson's
	Estraderm	estradiol	Antineoplastic; Hormone Used to relieve signs of menopause
	Exelon	rivastigmine tartrate	Cholinesterase Inhibitor (Central Nervous System Agent) Used to treat the symptoms of mild to moderate Alzheimer's disease
	Femara	letrozole	Antineoplastic Used to treat certain types of breast cancer in women
	Lamisil	terbinafine hcl	Antifungal Agent Used to treat fungus infections of the scalp, body, groin, feet, fingernails, and toenails
	Lamprone	clofazimine	Antibacterial Agent Used to treat leprosy
	Lescol	fluvastatin sodium	HMG-CoA Reductase Inhibitor (Cardiovascular Agent) Used to lower levels of cholesterol and other fats in the blood
	Lotensin	benazepril hcl	ACE Inhibitor (Cardiovascular Agent) Used to treat hypertension
	Lotensin HCT	benazepril & hctz	ACE Inhibitor (Cardiovascular Agent) Used to treat hypertension
	Lotrel	amlodipine besylate- benazepril hcl	ACE Inhibitor (Cardiovascular Agent) Used to treat hypertension
	Miacalcin	calcitonin (salmon)	Calcitonin (Hormone) Used to treat Paget's disease of bone. Also used to prevent continuing bone loss in women with postmenopausal osteoporosis and to treat hypercalcemia



Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Use
	Parlodel	bromocriptine mesylate	Antidyskinetic Agent; Antihyperprolactinemic; Growth Hormone Suppressant Used to treat certain menstrual problems or to stop milk production. Also used to treat infertility and Parkinson's disease
	Ritalin	methylphenidate hcl	Central Nervous System Stimulant Used to treat attention-deficit hyperactivity disorder (ADHD) and narcolepsy
	Starlix	nateglinide	Antidiabetic Agent Used to treat a type of diabetes mellitus (sugar diabetes) called type 2 diabetes
	Tegretol	carbamazepine	Anticonvulsant; Antipsychotic (Psychotherapeutic Agent) Used to control some types of seizures in the treatment of epilepsy
	Trileptal	oxcarbazepine	Central Nervous System Agent; Anticonvulsant Used in the treatment of partial seizures
	Vivelle	estradiol	Antineoplastic; Hormone Used to relieve signs of menopause
	Vivelle-DOT	estradiol	Antineoplastic; Hormone Used to relieve signs of menopause

## 1. Novartis Has Been the Target of Government Investigations

447. In connection with its scheme to inflate AWP's, Novartis has been investigated by the Office of Inspector General of the Department of Health and Human Services. The Office of the Inspector General published a report for the Department of Health and Human Services in 2000 documenting Novartis' inflated AWP for Aredia, its brand of pamidronate disodium.

## 2. Inflated Novartis AWP's From Novartis Price Lists

448. As set forth above, Novartis' scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

**Q. Pfizer**

449. Pfizer engages in an organization-wide and deliberate scheme to inflate AWP and has stated fraudulent AWP for many of its drugs. The specific drugs of Pfizer for which relief is sought in this case are set forth in Appendix A, and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
PFIZER	Accupril	quinapril hcl	ACE Inhibitor (Cardiovascular Agent) Used in the treatment of hypertension
	Cardura	doxazosin mesylate	Autonomic Nervous System Agent Used to treat hypertension and benign prostatic hypertrophy
	Eurostep FE	norethindrone-ethinyl estradiol-fe	Oral Contraceptive Also used in the treatment of acne
	Femhrt 1/5	ethinyl estradiol-norethindrone acetate	Estrogen Combination (Hormone) Used in the treatment of menopause and prevention of postmenopausal osteoporosis
	Lipitor	atorvastatin calcium	Antilipemic Agent (Cardiovascular Agent) Used to lower cholesterol
	Nardil	phenelzine sulfate	Antidepressant (Psychotherapeutic Agent) Used in the treatment of depression
	Neurontin	gabapentin	Anticonvulsant Used in the treatment of epilepsy
	Zithromax	azithromycin	Macrolide Antibiotic Agent (Anti-Infective Agent) General antibiotic
	Zoloft	sertraline hcl	Serotonin Reuptake Inhibitor (Psychotherapeutic Agent: Antidepressant) Used in the treatment of depression
	Zyrtec	cetirizine hcl	Antihistamine Used in the treatment of allergic rhinitis

450. Pfizer manufactures and distributes some of the nation's most popular and highest selling brand name drugs.

451. Historically, Pfizer almost never changes the "spread" between the posted AWP and posted WAC for a Pfizer brand name product. Once initially launched, a Pfizer brand name product continues to bear the same difference between the posted AWP and the posted WAC (e.g., 16 2/3%, or 20%, or sometimes 25%).



452. In January 2002, Pfizer announced a prescription drug discount card that would be available to elderly and poor consumers along eligibility criteria similar to that of other discount cards.

453. At the same time, January 2002, Pfizer secretly increased the AWP/WAC spread to 25% for *all* of its brand name drugs. If a drug theretofore had a posted AWP/WAC spread of 20%, it was increased to 25% (something which Pfizer, and indeed all other drug companies, almost never do). If a Pfizer brand name drug already had had a 25% AWP/WAC spread, it remained so.

454. By doing so, Pfizer knew that the purpose and effect of these new listings would be to increase reimbursement payments by end payors by amounts that would be greater than actual transaction costs for other participants in the distribution chain (*i.e.*, wholesalers, distributors, pharmacies and PBMs). Also in doing so, Pfizer knew that the posted AWP's for many of their brand name drugs would become more misrepresentative of actual average wholesale prices given that the increased AWP/WAC spread bore no relation to actual transaction cost changes occurring in the marketplace.

455. Pfizer has been investigated by the Office of the Inspector General of the Department of Human Health Services and has entered into a \$49 million settlement arising from illegal practices with respect to Lipitor. OIG-HSS found that Pfizer has been providing unrestricted educational grants and rebates that were in fact discounts off the purchase price of Lipitor. Pfizer concealed these discounts from states who were entitled to receive the "best price" for Lipitor.

456. The provision of educational grants and rebates on Lipitor also had the effect of inflating the reported AWP.





457. On information and belief, based in part due to the substantial nature of the spreads between AWP and WAC identified in Appendix A, Pfizer has inflated its AWP on other drugs at issue.

**R. The Pharmacia Group (Pharmacia and P&U)**

458. The Pharmacia Group engages in an organization-wide and deliberate scheme to inflate AWP. The Pharmacia Group has stated fraudulent AWP for all or almost all of its drugs, including those set forth below. The specific drugs of The Pharmacia Group for which relief is sought in this case are set forth in Appendix A, and are set forth below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
PHARMACIA GROUP (Pharmacia and P&U)	Adriamycin	doxorubicin hydrochloride	Antineoplastic Used in the treatment of various forms of cancer
	Adrucil	fluorouracil	Antimetabolite; Antineoplastic Used in the treatment of various forms of cancer
	Amphocin	amphotericin b	Antifungal (Anti-Infective Agent) Used in the treatment of serious fungal infections
	Celebrex	celecoxib	Analgesic; Antirheumatic Agent Used to relieve some symptoms caused by arthritis
	Cleocin-T	clindamycin phosphate (topical)	Antibacterial Agent (Anti-Infective Agent) Used to treat bacterial infections
	Cytosar-U	cytarabine	Antineoplastic Used in the treatment of cancer of the blood
	Depo- Testosterone	testosterone cypionate	Androgen (Hormone) Used to replace hormones or stimulate growth
	Neosar	cyclophosphamide	Alkylating Agent (Antineoplastic) Used in the treatment of various forms of cancer as well as some kidney disease
	Solu-Cortef	hydrocortisone sodium succinate	Anti-Inflammatory Agent; Skin and Mucous Membrane Agent Used to provide relief for inflamed areas of the body. Also used as replacement therapy in adrenocortical insufficiency





Manufacturer	Brand Name (Trade Name)	Generic Name	Pharmacologic Category/Usage
	Solu-Medrol	methylprednisolone sodium succinate	Anti-Inflammatory Agent Used to provide relief for inflamed areas of the body. Also used as replacement therapy in adrenocortical insufficiency
	Toposar	etoposide	Antineoplastic Used in the treatment of testicular and lung cancer
	Vincasar	vincristine sulfate	Antineoplastic Used in the treatment of various forms of leukemia and cancer
		bleomycin sulfate	Antineoplastic; Antibiotic Agent (Anti-Infective Agent) Used in the treatment of various forms of cancer

### 1. The Pharmacia Group Has Been the Target of Government Investigations

459. In connection with its scheme to inflate AWP's, The Pharmacia Group has been investigated by the Department of Justice, the Texas Attorney General, the California Attorney General, the Massachusetts Attorney General, the Attorney General of the State of Connecticut, the Attorney General of the State of New York, and the Department of Health and Human Services Office of Inspector General.

### 2. Pharmacia's Definition and Understanding of AWP

460. Pharmacia understands that third party reimbursement is based on its published AWP's. According to a "Strategic Presentation on Average Wholesale Price (AWP)" prepared by P&U, the "Definition of AWP" is:

An artificial pricing index that is used as a common basis for third-party reimbursement to pharmacists and physicians.

-The difference between the published AWP (less a percentage) and the direct price is the profit margin that drives these classes of trade.

(PH 025785) (Highly Confidential). During this same presentation, Pharmacia provided an "AWP History":



- ◆ Historically, Wholesalers viewed AWP as an actual average selling price to their customers.
- ◆ Competition of 1980's led to AWP representing a "Suggested List Price"
- ◆ P&U AWP = 125% of Direct Price (DP)
- ◆ Exceptions being VANTIN, CVC, GENOTROPIN, and RESCRIPTOR = 120% of DP

(PH025791) (Highly Confidential). Further, the presentation recognized that "'95 Medicare (Part B) outpatient drug bill (I.V./inhalants/oncolitics/nutritionals) of \$1.8 billion based primarily on AWP.'" (PH025793) (Highly Confidential).

### **3. The Pharmacia Group Controls the Published AWP for Its Products**

461. The Pharmacia Group has controlled and set the AWP's for its pharmaceutical products through direct communications with industry compendia during the Class Period. In its presentation entitled "Strategic Presentation on Average Wholesale Price (AWP)," P&U included a flow chart that shows P&U communicates its AWP's to First Data Bank, Medi-Span and *Red Book*. This same flow chart then shows that third party payors rely on these industry compendia for prices. (PH025792) (Highly Confidential).

### **4. The Pharmacia Group's AWP Manipulation Benefited Providers at the Expense of the Class**

462. The Pharmacia Group has engaged in an ongoing deliberate scheme to inflate AWP's. According to one member of the Congressional Ways and Means Committee:

The evidence . . . indicates that [Pharmacia & Upjohn] have knowingly and deliberately inflated their representations of the average wholesale price ("AWP"), wholesale acquisition cost ("WAC") and direct price ("DP") which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers.

\* \* \*

[T]hese practices must stop and . . . these companies must return the money to the public that is owed because of their abusive practices.



See Extension of Remarks of U.S. Representative Pete Stark in the House of Representatives, October 3, 2000 (P007545-P007547).

463. In a letter dated October 3, 2000 to Pharmacia (with accompanying exhibits), Representative Stark addressed the Pharmacia Group's illegal practices:

The manipulated disparities between your company's reported AWP's and DP's are staggering. For example, in 1997, Pharmacia & Upjohn reported an AWP of \$946.94 for 200 mg. of Adriamycin PFS while offering to sell it to American Oncology Resources (AOR) for \$168.00 and to Comprehensive Cancer Center for \$152.00 (Composite Exhibit "1"). Your company then aggressively marketed its cancer drugs to health care providers by touting financial inducements and other types of incentives. Pharmacia & Upjohn created and marketed the financial inducements for the express purpose of influencing the professional judgment of doctors and other health care providers in order to increase the company's market share.

\* \* \*

Pharmacia & Upjohn's own internal documents . . . reveal that the company abused its position as a drug innovator in an initial *Phase III* FDA clinical trial for a cancer drug used to treat lymphoma (Composite Exhibit "2") (emphasis in original).

" . . . Clinical Research Trials

Initial Phase III Protocol trial for "Oral Idamycin" in lymphomas. This trial will offer AOR \$1.1M [million] in additional revenues. Two hundred twenty-five (225) patients at \$5,000 per patient . . . (emphasis added by Rep. Stark)

The above . . . items are contingent on the signing of the AOR Disease Management Partner Program. AOR's exclusive compliance to the purchase of the products listed in the contract product attachment is also necessary for the above items to be in effect."

The linking of doctor participation in FDA clinical drug trials to their purchase and administration of profit-generating oncology drugs is entirely inconsistent with the objective scientific testing that is essential to the integrity of the trial.

\* \* \*